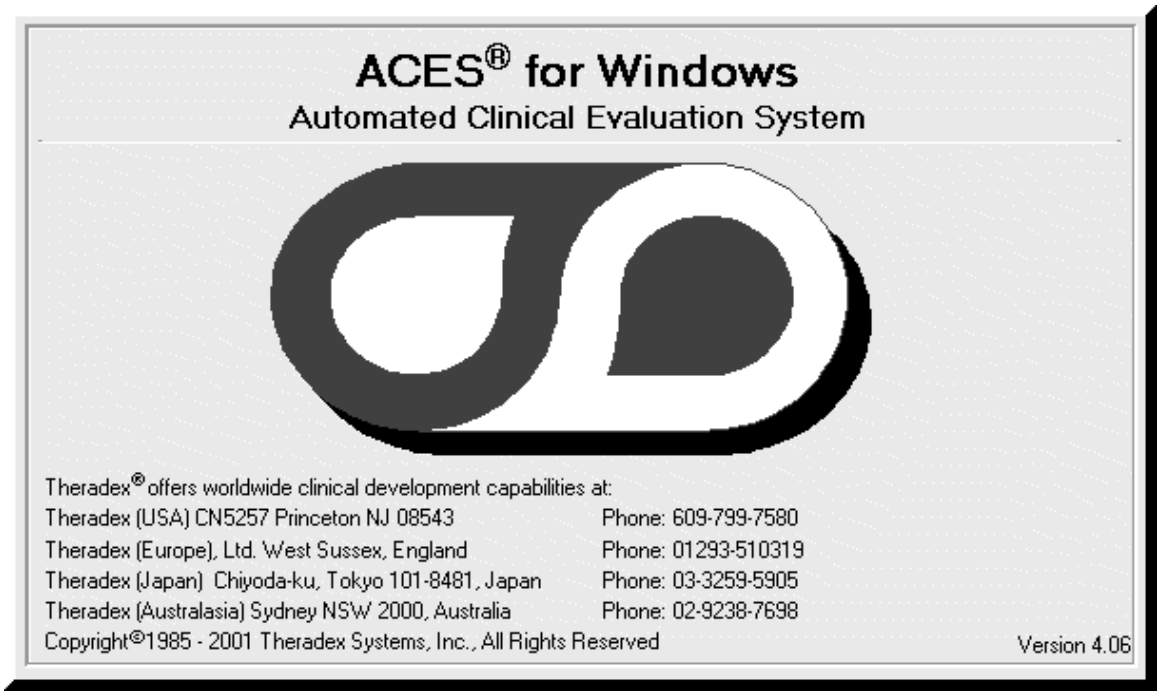

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INTRODUCTION

ACES®(1) for Windows is an application package designed to collect, transmit, and report clinical oncology research study data. This system works in conjunction with the Relay Gold(2) communications software package. There are additional computer hardware and software requirements necessary to install and use the system. In general, it requires 16 megabytes of random access memory (RAM) and runs on most Windows 95®, Windows 98®, and Windows NT®(3) compatible microcomputers. In addition, ACES® has been validated to run on certain local area networks (LANs). Electronic data storage requirements include a minimum of 20 megabytes (MB) of hard disk storage, but could easily run to more, depending on the amount of data collected.

ACES® for Windows has been designed by Theradex®, in concert with the Investigational Drug Branch of the National Cancer Institute. ACES® provides an electronic version of the NCI approved Phase I/II Case Report Form. The Case Report Form has been drawn up to include the items which are commonly reported to the Clinical Trials Monitoring Service. Both the Case Report Form and the electronic version of the Case Report Form contain many items that may not be relevant to each and every Phase I/II study. The Electronic Case Report Form (ECRF) is sectionalized into portions of the whole form, so that the investigator may select the appropriate portions for any given study. ACES® has been designed in a modular manner in order to easily add, delete, or modify procedures, as needed. It is currently tailored to oncologic trials, but can be adapted for any therapeutic assessment of disease.

In addition to the data collection function, the current version provides the facilities to extract data, prepare it for transmission to a central database, generate summary reports, validate data at time of entry, and integrate data collected on multiple computers to a single location.

ACES® is available through Theradex Systems, Inc., upon request.

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(1)ACES is a trademark of Theradex Systems, Inc.
(2)Relay Gold is a trademark of Relay Technology, Inc.
(3)Windows 95, Windows 98 and Windows NT are trademarks of Microsoft Corporation

THERADEX® - HISTORY

Theradex® was founded in the United States in 1982 by Dr. Robert B. Royds, and remains the only major contract research organization in the world specializing primarily in clinical oncologic studies. For over fifteen years, we have held the Clinical Trials Monitoring Service Contract for the National Cancer Institute in the United States and in that time have gained a wealth of experience in the treatment of cancer and allied diseases.

We opened the first of our international subsidaries-Theradex® (Europe) Ltd.-in 1992 as part of our global development in life-threatening diseases, particularly cancer. In 1993, we opened Theradex® (Japan)-our liaison office in Tokyo. And in 1995, we established Theradex® Australasia Pty. Ltd., based in Sydney.

Because of the Company's close affiliation with the U.S. National Cancer Institute and the EORTC, NDDO (New Drug Development Office), SENDO (Southern Europe New Drug Organization), and ECTG (Early Clinical Trials Group) in Europe, it is natural that the focus of our worldwide activities continues to be in areas of oncology and biologics.

THERADEX® - CAPABILITIES

On behalf of both domestic and overseas clients, Theradex® can provide a comprehensive array of services. Any portion of these capabilities can be provided to the pharmaceutical industry on an as needed basis:

•Prepare all necessary regulatory filings
•Negotiate resolution of FDA questions
•Select investigators/study sites
•Initiate studies
•Write protocols
•Design Case Report Forms
•Monitor single institution or multicenter studies Phases I through IV
•Collect all required data
•Assure the numerical validity using statistical techniques
•Perform statistical analyses
•Select and administer quality-of-life instruments
•Write narrative reports
•Write overall summaries
•Develop new assessment techniques for drugs and diagnostic/prognostic antibody tests
•Perform pharmacoeconomic analyses
•Incorporate automated phone registration using a computerized patient randomization and registration system

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CLINICAL TRIALS MONITORING SERVICE (CTMS)

Theradex® has administered the CTMS under contract with the National Cancer Institute (NCI) since 1982, and is currently operating under the fourth five-year contract. This project has many facets, and involves a number of services, some of which are listed below:

1. Perform all ongoing requirements on behalf of the sponsor for Phase I Chemotherapeutic Studies and Phase I-II Biological Studies, ensuring:

•Fulfillment of all regulatory requirements •Secure and adequate pharmacy procedures •Adequacy of institutional review and consent procedures •Verification of laboratory competency •Thrice yearly verification of individual study data submitted to Theradex® by investigators

2. Evaluation of the compliance of such studies, including:

•Eligibility of all patients •Evaluability of all courses of treatment •Review the compliance of each investigator

3. Quality Assurance of incoming data from:

•Our remote data entry system, ACES® •Case Report Forms submission

4. During the conduct of this contract, the scope has been expanded at the request of the U.S. Government/NCI to include:

•Maintenance of all the extramural IL-1/LAK Cell development studies •Maintenance of all the intra and extramural IL-2/TIL Cell development studies •Institution of new procedures for evaluation of scintigraphic monoclonal antibody techniques which visualize minimal malignant disease •Development of new procedures for evaluating the effect of Colony Stimulating Factors on the diminution of infectious episodes and other indicators of morbidity

5. CTMS also involves:

•Conducting Cancer Center visits to evaluate protocol compliance, response assesments, regulatory issues and investigational drug handling by all US Cancer Centers conducting research under an NCI-held IND or funded by NCI, generally performed every 3 years •Co-monitoring of ~20% of all US Cooperative Oncology Groups site visits

SOFTWARE UPDATES

Improvements to ACES® will be made available to registered users periodically. These updates are available on 1.44MB 3 ½" diskettes.

TECHNICAL SUPPORT

Technical support is available to users by calling Theradex® at (609) 799-7580. Ask the operator to connect you to an ACES® Hotline staff member.

HARDWARE REQUIREMENTS

Windows 95® , Windows 98® or Windows NT® compatible personal computer

Pentium® or Pentium –class processor required

20 MB minimum disk space

Color display

Internal clock/calendar

Asynchronous communications port (for modem transmission)

Local or networked laser printer recommended

16 MB RAM – minimum

Modem - autodial 9600 or higher baud Hayes compatible

SOFTWARE REQUIREMENTS

Windows 95® , Windows 98® or Windows NT®

Novell NetWare(2) for multi-user installations (Optional)

ACES® for Windows, Automated Clinical Evaluation System

Relay Gold, communication program (for modem transmission)

ACESLINK, package of communication scripts (for modem transmission)

(1)Pentium is a registered trademark of Intel Corporation.
(2)NetWare and Novell are registered trademarks of Novell, Inc.

QUICK START PROCEDURE

In order to begin using ACES® for Windows, there are a few basic steps that must be completed, as follows:

1. Install ACES® for Windows.
2. Run ACES® for Windows from the "Programs" menu.
3. Add appropriate user names, passwords, and privileges.
4. Load the Protocol Startup diskette, and, optionally, the Lab Startup diskette. If no Lab Startup disk is available, enter the laboratory normal ranges to be used for the study.
5. Select the Protocol, Patient, and Course for data entry. Subsequently, notice that the Sequence Bar will be displayed on the right side of the screen. This indicates which forms need to be completed for the selected protocol, patient, and course.
6. Select a database and perform the necessary entry. When entry for a form is complete for the selected patient and course, click on the NEXT DB button on the browse window (or select "Database" from the Edit menu) and select the next form for entry.
7. Weekly, or as needed by the protocol, run the "Transfer to Data Center" procedure to extract a copy of your new or updated data.
8. Send this transfer data to the central data center on diskette, or by modem using ACESLINK.

WORKSTATION SECURITY

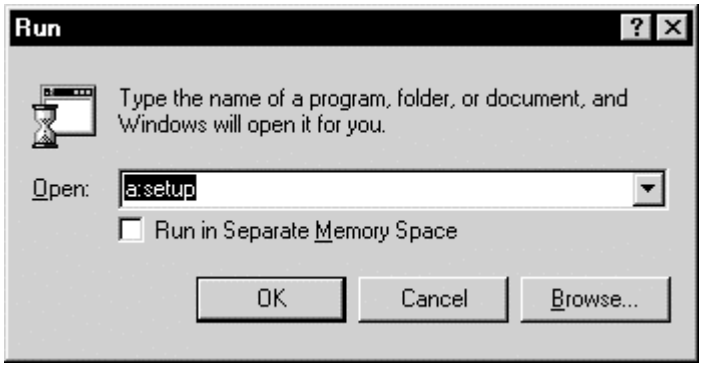
The GCPs require that systems on which clinical data may be viewed have some facility to blank the screen after a certain period of inactivity, requiring a password to re-activate. ACESWin may have such a system built into it in the future. In the meantime, we ask that all users setup their Windows screen saver with a password, thereby meeting the FDA requirements.

1. Click on the Start button, then choose Settings.
2. Select Control Panel.
3. Double click on the Display icon.
4. Click on the Screen Saver tab.
5. Click on the Password Protected checkbox if it is not already checked.
6. Click on the Change button to add or update a password.
7. Click on the OK button to save your Display changes, then close the Control Panel.

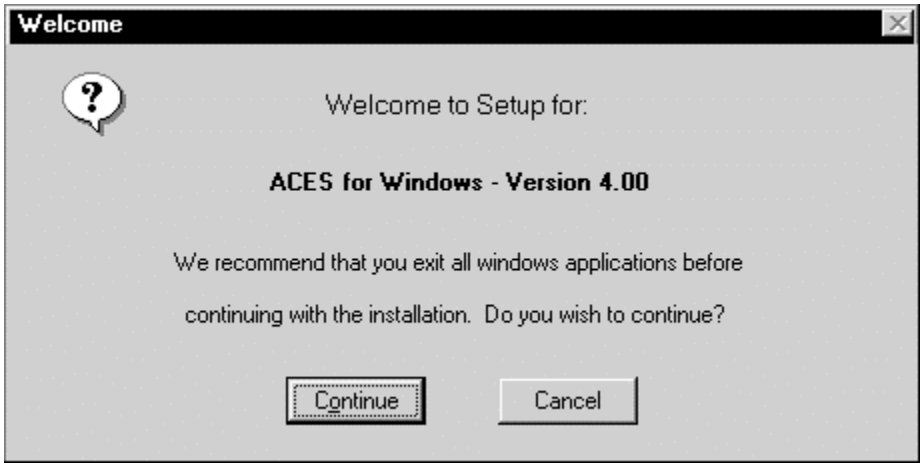
Once your screen saver is activated, you will need to enter your password to return your screen to normal.

INSTALLATION

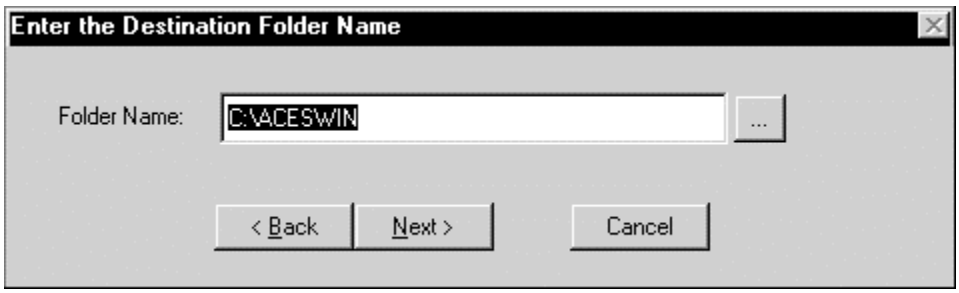
To install the software, insert Disk 1 into the A: diskette drive and click the START menu. Then, select the RUN option. Enter "A:SETUP" into the "Run" dialog box, which will be similar to the following:



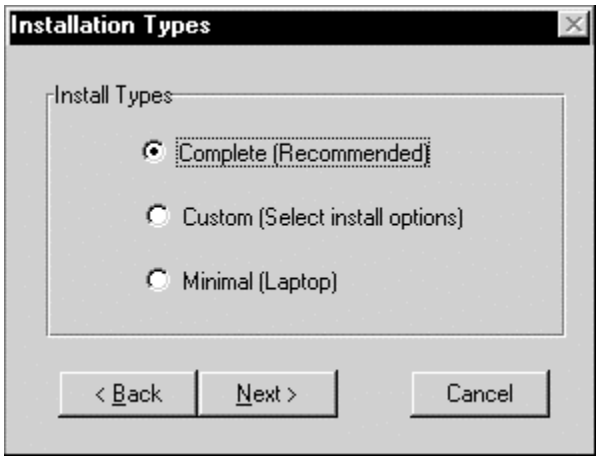
Click the OK button to begin installation. Subsequently, the "Welcome" screen, similar to the figure below, will be displayed:



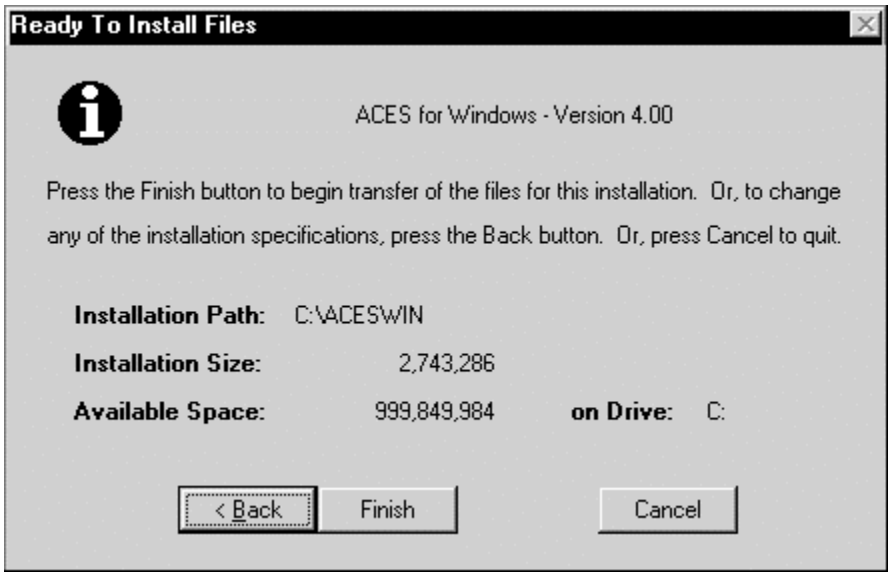
Click the "Continue" button to proceed. Subsequently, you will be prompted to enter the installation path. Unless your system administrator has a preference, press Enter to accept the default path of "C:\ACESWIN", as shown below:



Click the “Next” button to proceed. The next dialog will prompt for Install Type, as follows:



In general, click the “Complete (Recommended)” option. Select “Custom (Select install options)” to run a partial install. Click the “Next” button to proceed. The next screen will display installation parameters, including the amount of free disk space available on your target drive. If there is not enough free space to install the program, you’ll need to cancel and free up some disk space. The screen appears similar to the following:

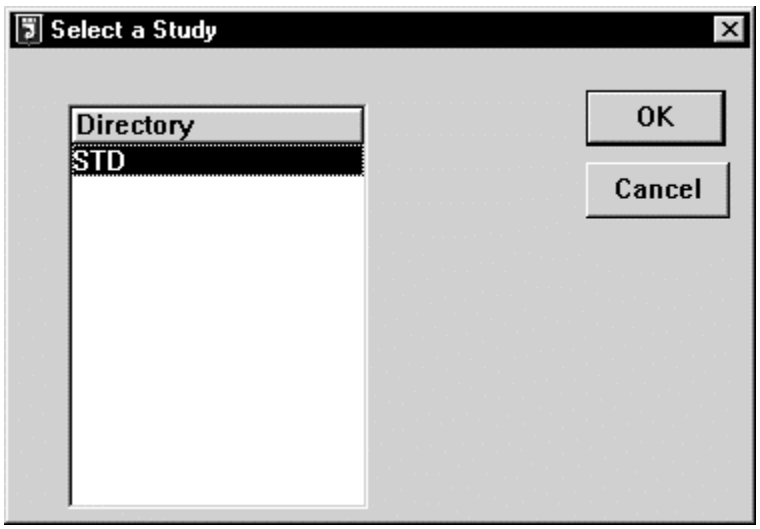


Click the “Finish” button to start copying files. You will be prompted to insert successive diskettes until the installation is complete. When all files have been copied successfully, a “File Transfer Complete” window will be displayed:

Click the “OK” button and the system will update your “Programs” menu to include “Aces for Windows” as an option. Installation is now complete.

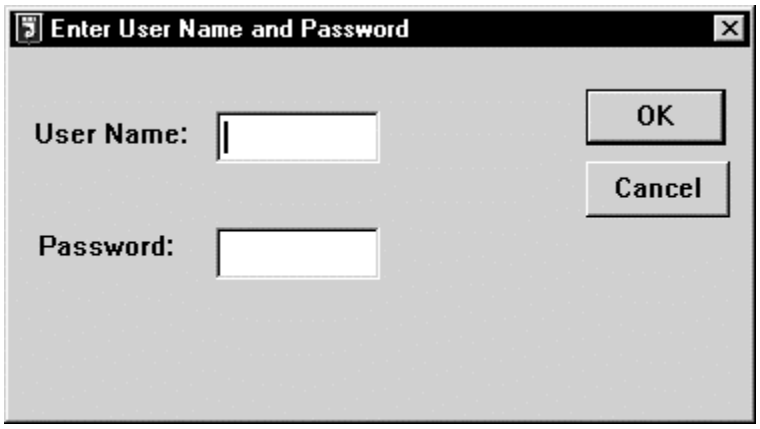
STARTING ACES

From the “Start” menu, select the “Programs” option, followed by the “ACES” selection from the “ACES for Windows” folder. The first window displayed is the “Select a Study” dialog, which will be similar to the following:



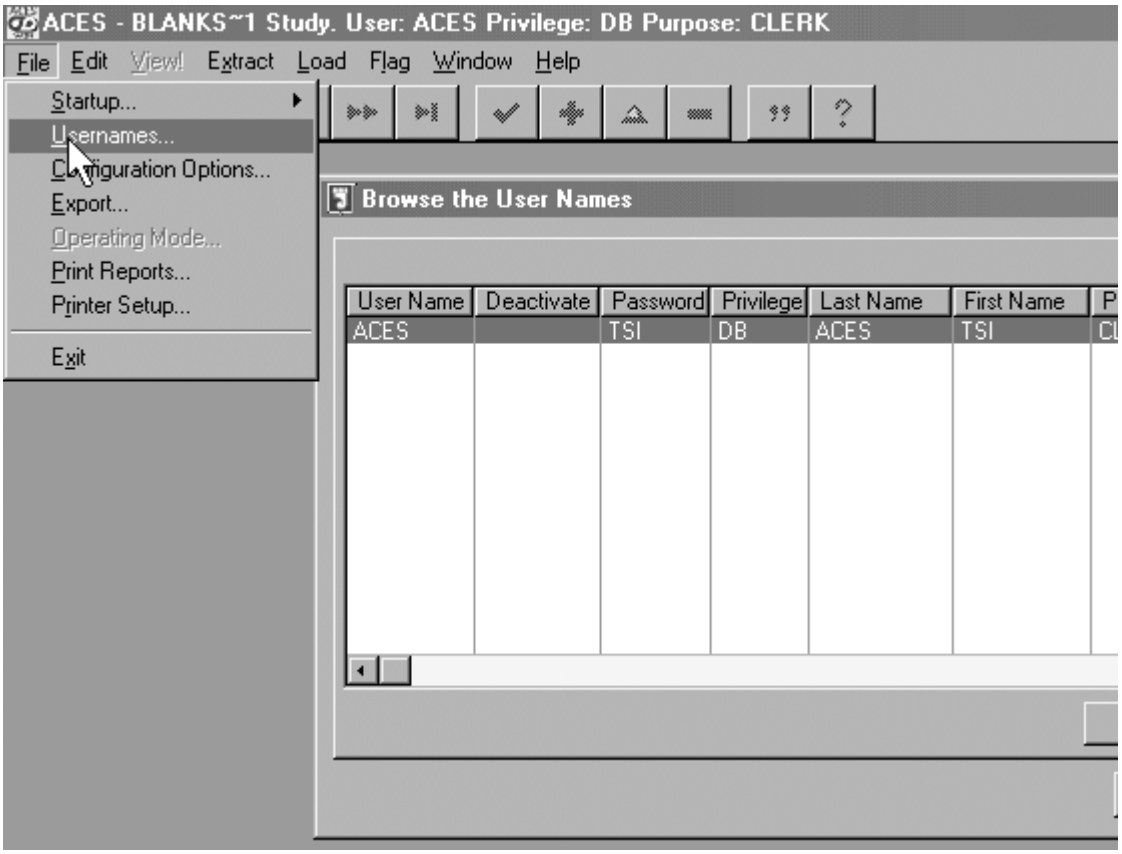
Highlight the desired study and click the OK button to proceed. Your installation will have one or more studies displayed, depending on the number of projects in use. After a study is selected, you will be prompted for a user name and password.

USER NAMES, PASSWORDS, AND PRIVILEGES



The default user name is “ACES” and the default password is “TSI”. Enter these values and click the OK button to proceed. Subsequently, the ACES® for Windows welcome screen will be displayed briefly, or you can press the Enter key, or click the mouse to continue. Help is available by clicking on the “Help” drop-down menu on the toolbar and is styled in the standard Windows help system format.

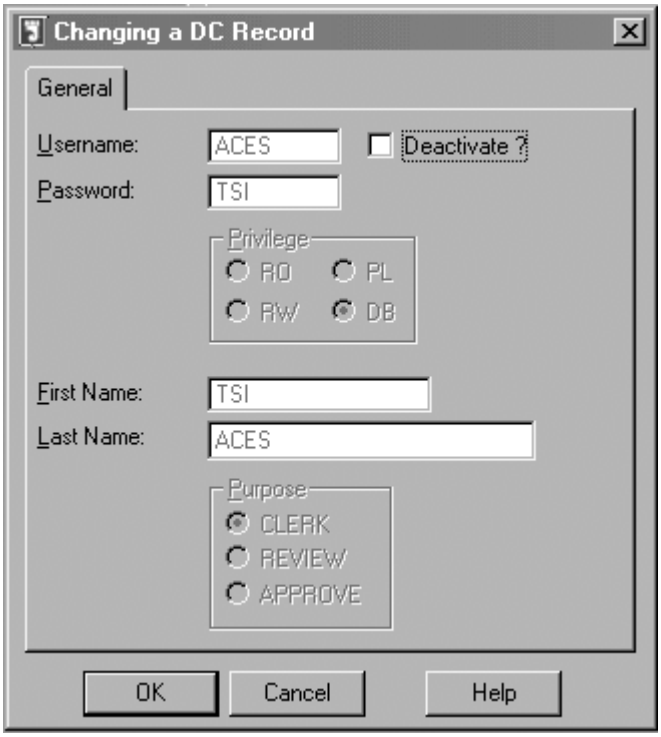
You’ll need to first add the user names and associated passwords, privileges, and purposes that apply to the selected study. You'll also need to deactivate the default user name (ACES) and password (TSI), otherwise unauthorized users may be able to access your data. Select the “File” menu and click the “Usernames” option to enter this information, as shown below:



Once a Username record is added, you may not change it in any way except to deactivate or reactivate. This preserves the integrity of the audit trail. Associated with each user name and password combination is a system access privilege. Choose one of read-only (RO), read/write (RW), pick list (PL), or database administrator (DB). A read-only user can view or report data. A read/write user can perform the read-only functions, and can also enter and extract data. A pick list user can alter or delete the edit checks associated with a particular study. A database administrator can't enter data, but can reconfigure the entire system. Therefore, a person with this type of access must be an expert user, since data can become permanently damaged if the wrong procedures are used. You'll also need to associate a purpose with each user. Choose "Clerk" (data entry), "Review" (data manager or study monitor), or "Approve" (investigator). **Please create a DB username and PL username for your institution, in addition to as many RW usernames as needed.** An RW username is typically the user's actual first name.

Example: suppose Jane Smith is a datamanager at the **Cure Hospital**. Jane might setup a RW username for herself called JANE, a RW username JOE for research nurse Joe Brown who sometimes helps with data entry, and a RO username MARY for Dr. Mary Jones. Jane may never need to alter the database or picklist structure of ACESWin, but just in case, she also sets up DB and PL usernames. She might choose JANEDB or CUREDB for the DB username, and JANEPL or CUREPL for the PL username. She should designate different passwords for all usernames. The passwords should not be easily guessed, but also something that she or the appropriate person won't forget.

You'll need to also click the "Deactivate" button for the ACES user so that this default username cannot be used. After setting up all needed usernames, it is recommended that you exit and re-enter ACES® before proceeding so that you are accessing the program using the correct set of privileges. A sample entry screen appears below:



Only DB users may access all Username records and add records of all types. RW and PL users may add new records with RW or RO privilege, but will only be able to deactivate their own record. RO users may not add new records or deactivate their own record.

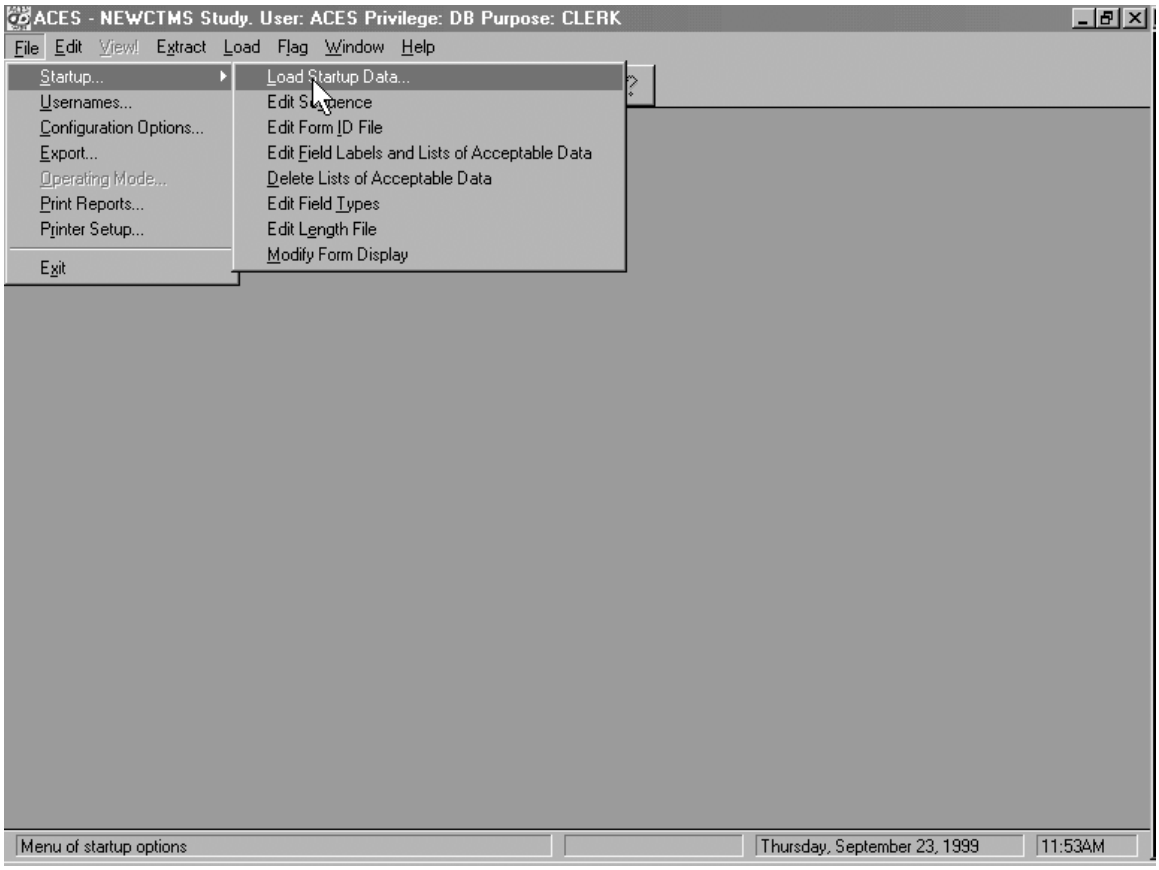
INITIATING A NEW STUDY

Most studies that collect data using ACES® are designed by a central data center, which is usually Theradex®. As a result of this design, you will have received several pre-configured data files, which were loaded during installation of the ACES® software. In addition, a Protocol, and, possibly, a Lab Startup disk should have been included in the study startup package. Before you can begin entering data for such a study, you'll need to, at a minimum, initialize the Protocol Abstract and Lab Normals files with the relevant information. You can do this in one of two different ways:

1. Load Protocol and Lab Startup diskettes.
2. Enter the information into the Protocol Abstract and Lab Normals files yourself.

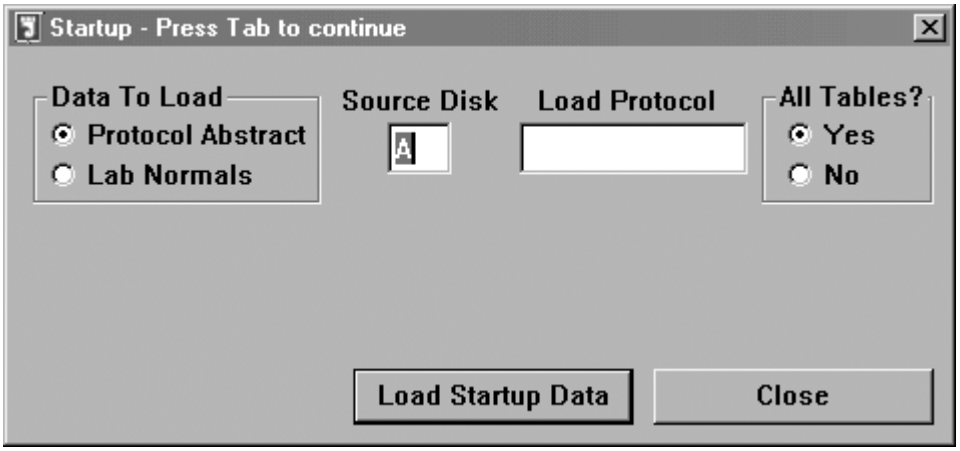
In general, you will be using option 1, at least for the Protocol Startup. If you'd like to design a new study yourself, please refer to the "HOW TO DESIGN A NEW STUDY" section.

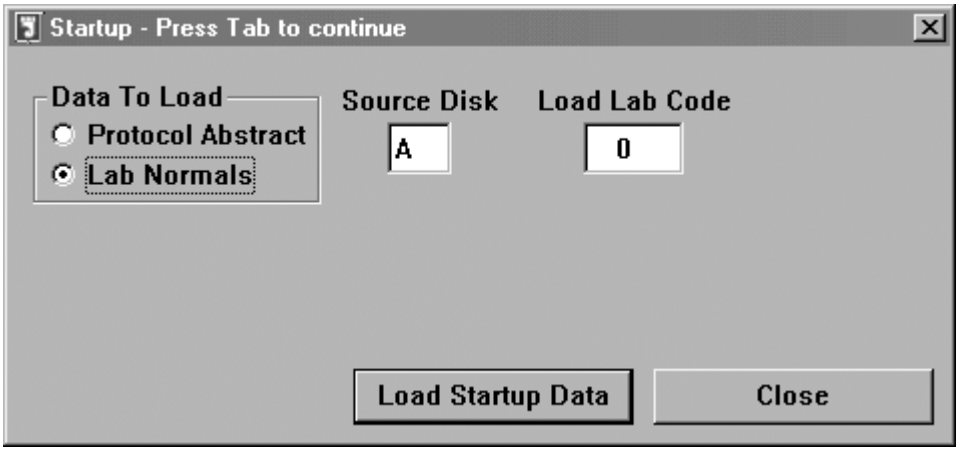
To load the information from a Protocol or Lab Startup diskette, insert the diskette into the A: diskette drive and select the Startup menu option from the File menu, followed by the Load Startup Data option, as shown below:



You can elect to load a Protocol or Lab Startup diskette. If the central data center has entered an initial set of laboratory normal ranges for the new study, you will have both a Protocol and a Lab diskette. In these cases, you'll need to run the procedure multiple times to load the Protocol and all available lab codes on the Lab diskette. Otherwise, you can enter your own set of laboratory normals for each lab being used. The

Startup screens look similar to the following. Click either the Protocol Abstract or the Lab Normals option. The Source Disk is the disk drive letter, usually "A", where you have inserted the Startup diskette. The Source Disk is the disk drive letter, usually "A", where you have inserted the Startup diskette. If you have received the startup files via email, copy them into your study's Exch directory and use "C" as the Source Disk. Enter the protocol number printed on the Startup diskette label, if loading a Protocol disk. In general, you will always answer "Yes" to load All Tables. For more information on the file choices available if you answer "No," see the section on Makedisk. If you are loading lab normal information, you will also need to complete the "Lab Code" field. If there are multiple lab codes on your Lab Startup diskette, you'll need to load each with a separate run of this procedure. Click the Load button when ready to begin loading. Below are sample Protocol and Lab Startup screens:



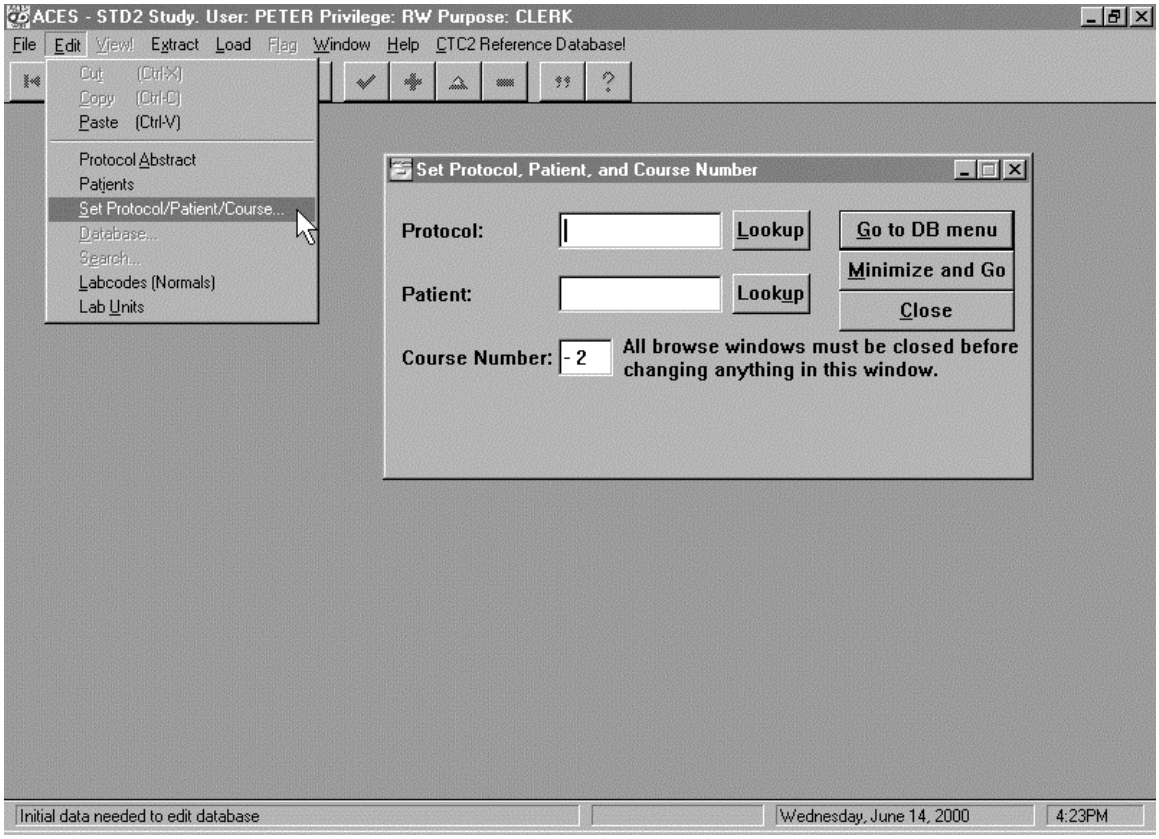


Note that during the Startup loading process, you will often see informational messages displayed. These messages usually indicate which files have not been included on the Startup diskette. In most cases, these messages can be ignored since, in general, protocols do not require information loaded for every study configuration file. If you have designed your own study using MakeDisk, created unique forms, and subsequently created a Startup disk for loading into ACESWin, then the absence of some or all of these configuration files may be relevant.

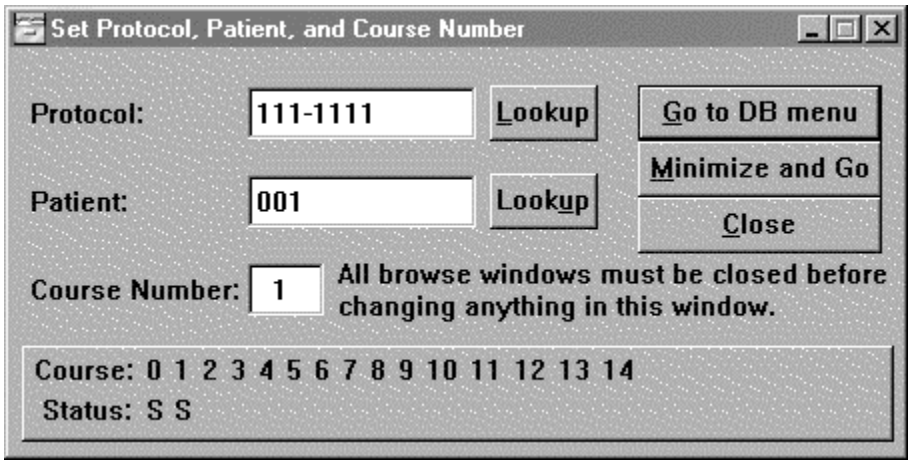
After loading lab normal information from a Lab Startup diskette, in order to make use of this data you'll need to copy it (using the "Labcodes (Normals)" menu item from the Edit menu) to stamp your site ID on it as the SiteID for LabCode. This process is done to avoid overwriting, and then transferring, lab normal information entered at another site. If this happens, there is the risk of having multiple sets of normal data existing with the same key identifiers.

SELECTING A PROTOCOL, PATIENT, AND COURSE

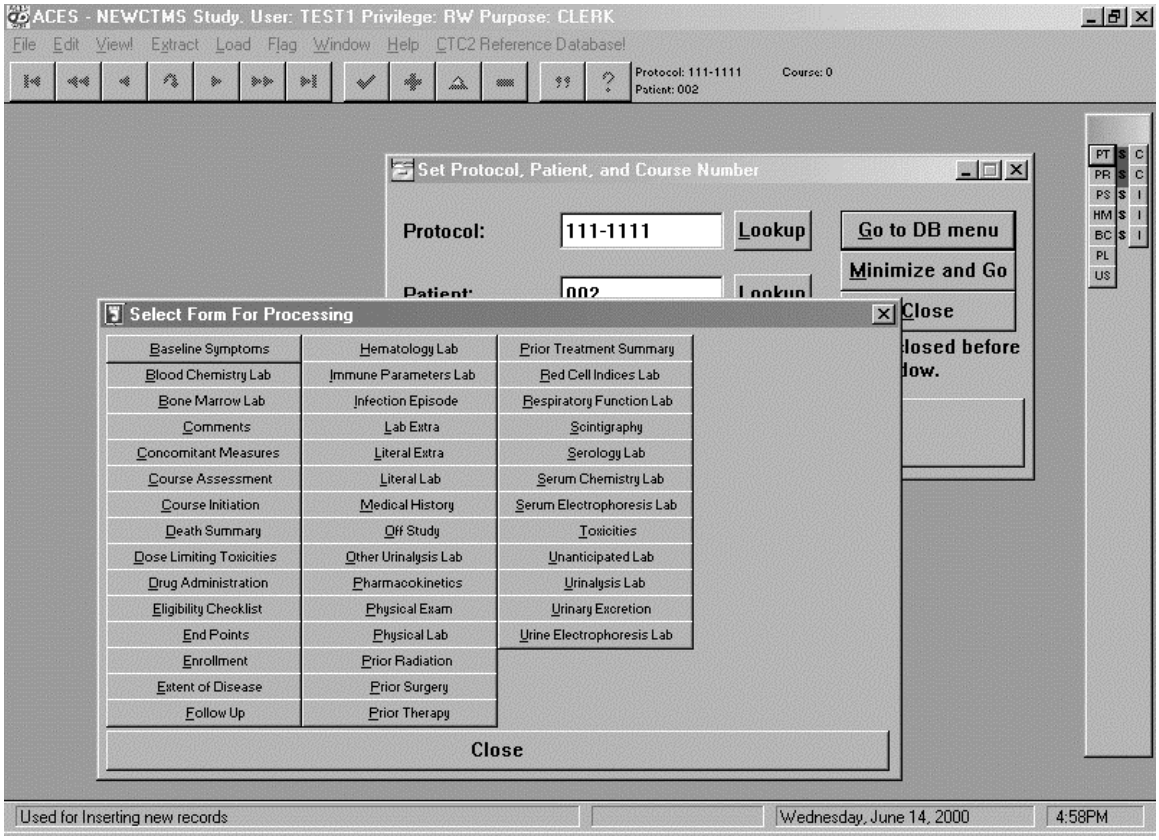
Once a study has been initiated, and has, therefore, a Protocol Abstract, at least one set of laboratory normal ranges, a selection of forms and associated fields (this is normally set up when ACES® is installed), and appropriate user names profiles, then entry of patient data can begin. The first step is to select the protocol, patient identifier, and course (or cycle). From the "Edit" menu, select the "Set Protocol/Patient/Course" option, as shown below:



You can enter a protocol and patient, or click the "Lookup" buttons to select from the list in the Protocol Abstract and Patient files. Once the patient identifier is entered, the screen will display a list of course numbers with associated status codes underneath, corresponding to the protocol selected. Then, enter the course number associated with the data to be entered. In the following window, courses 0 (baseline) and 1 have been started (code = S). Other codes are blank (no entry has been done) or "C" (information for this course has been completed). Once all courses have a "C" code (which is a decision made by the data manager), then entry for the associated patient should be complete. In the case of studies converted from a prior version of ACES in which course number was not collected in all forms, it is permissible to leave the course number as -2.



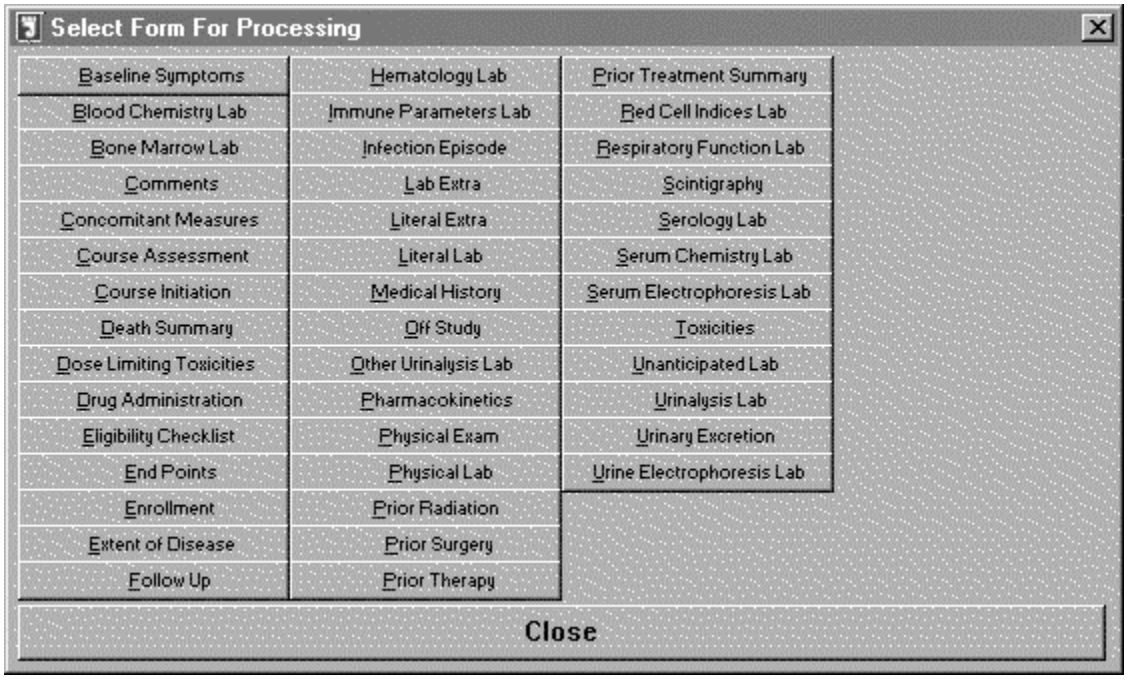
Click either the "Go to DB menu" or "Minimize and Go" buttons to proceed. Pressing Enter is equivalent to clicking on "Go to DB menu." The Set Protocol, Patient, and Course Number window will stay open if the "Go to DB menu" button is clicked, while if "Minimize and Go" is chosen, the window will be minimized to the bottom left side of your screen. Minimization is suggested if you don't like a cluttered desktop space. If the course number is not -2 and thus 0 or greater, the main ACES® window will now include the vertical Sequence Bar on the right side of the screen. This bar will include the form identifier for each form requiring entry for the selected protocol, patient, and course. To the right of each identifier are two columns. The first will be blank (indicating no entry has been done for the associated form), or will have an "S" (indicating data entry has been started, but not completed, for the form). The second column will be blank (again no entry), have an "I" (entry has been started but is incomplete), or a "C" (entry is now complete for this patient, course, and form). An example is shown below where entry is complete for the PT (prior therapy) and PR (prior radiation) forms, started for the PS (prior surgery), HM (hematology), and BC (blood chemistry) forms, and no entry has been done for the PL (physical lab) or US (urinalysis) forms.



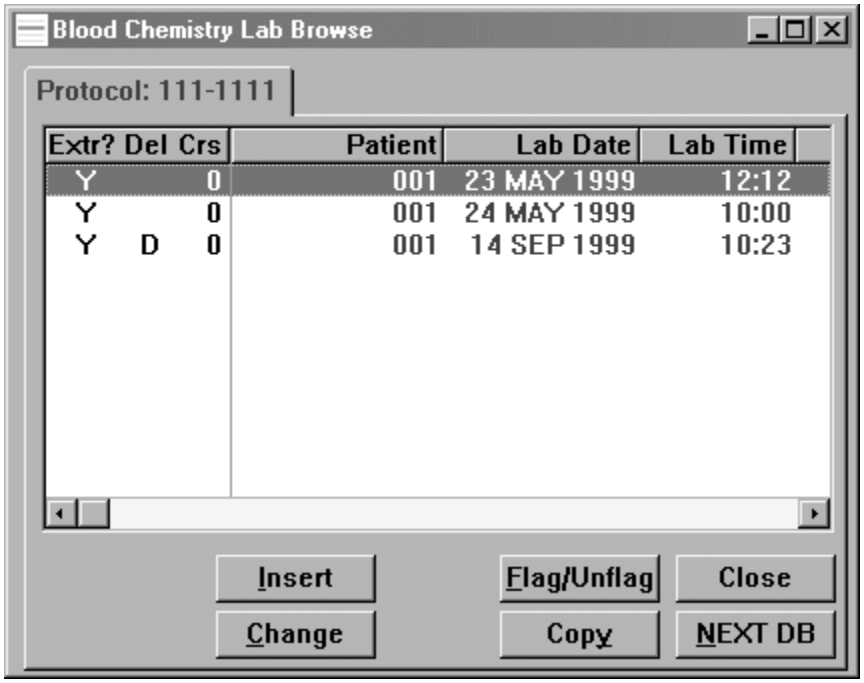
If your privilege is RW or RO, the database menu will appear (as shown above), allowing you to choose a database to browse. Once the Protocol, Patient, and Course are set, you may choose "Database" from the "Edit" menu at any time or click on the "Go to DB menu" button on the Set Protocol, Patient and Course Number window to cause the database menu to appear. This allows you to edit more than one form at the same time if desired. If you wish to change the protocol, patient or course number, you must close all open browse windows first. If your privilege is DB, you may click on the "View!" menu to view the database, but you may not edit it. **Note that the database menu does not appear if a DB user clicks on the "Go to DB menu" or "Minimize and Go" buttons.** The View! menu is available for any user as soon as a protocol and patient number have been entered; the course number is not necessary for viewing.

ENTERING PATIENT DATA

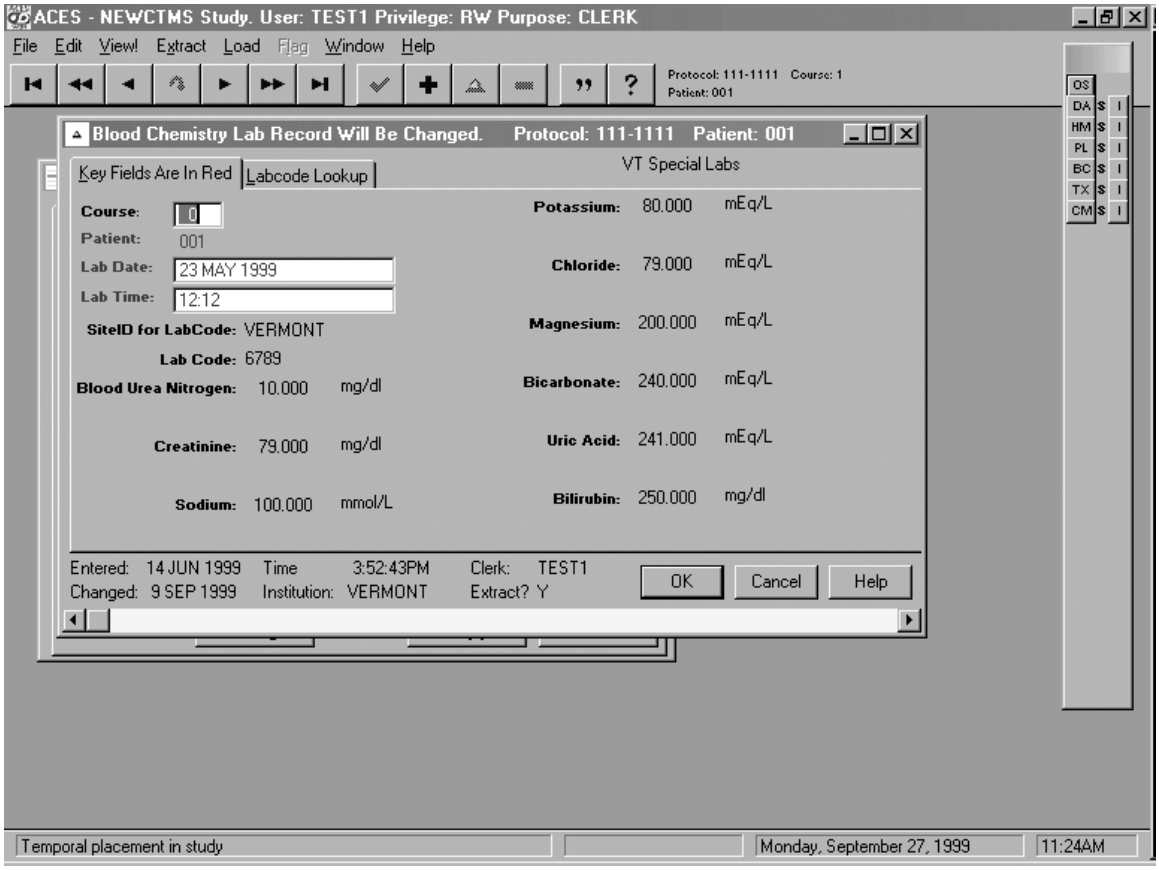
From the "Edit" menu, select the "Database" option or click on the "Go to DB menu" button on the Set Protocol, Patient and Course Number window to begin entering patient data. [If "Database" is not available (grey instead of black) or the Set Protocol, Patient and Course Number window is not open and your privilege is RW or RO, then see "SELECTING A PROTOCOL, PATIENT, AND COURSE."] Subsequently, a menu of valid forms will be displayed. A sample is shown below:



Select the desired form by clicking on it, or alternatively, type the first letter of the desired form until selected, then press Enter. (The tab and shift-tab keys may also be used to navigate the menu.) Note that the form names are organized alphabetically, and the two character abbreviations are no longer used to select the form (as in ACES® DOS). The browse screen for the associated form will be displayed in the first window. You have options to insert, flag for deletion or undeletion, change, or copy a record. You may also click on the NEXT DB button to close this browse window and bring up the database menu to select the next form. You can page up and down through the file also. The "Extr?" column will have a "Y" printed in it if the record needs to be extracted for delivery to the data center. This flag is controlled by the software and is reset whenever a record is added, changed, or flagged for deletion or undeletion. The "Del" column will have a "D" listed if the record is flagged for deletion. ACES® does not erase records that need to be deleted, but adds a deletion flag. The purpose for this is to maintain an accurate audit trail, and to assure that the central data center (if one is participating in the study) can be electronically notified of all deleted records. A sample browse window for the BC (Blood Chemistry Lab) form is shown below:



After an existing record is selected for change or flagging, or an insert function selected to add a new record, the associated entry form will be displayed. A sample entry form for the blood chemistry lab (BC) file would look similar to the following:



Use the tab key, or your mouse, to proceed forward through the entry fields. Tabbing from the last field on an entry screen will automatically display succeeding entry screens, if any. All date fields must be entered using the international date format. Note that fields with an associated picklist are designated as such by an underlined field label. Pressing the F10 function key will bring up the picklist for the current field. After the data entry is complete, click the "OK" button or press the Enter key. Also, notice the administrative fields displayed at the bottom of the window. Each record keeps track of the first entered date, and the last changed date, time, institution code, and clerk name. Click on the NEXT DB button on the browse window to select the next form for data entry. Take note of the Sequence Bar when entering data. When you first enter data into a form, the Sequence Bar will display an "I" in the second column, indicating entry is started, but incomplete. This will happen automatically. When you have completed entry for a particular protocol, patient, form, and course, click the "I" box in the Sequence Bar. This will change the "I" to a "C", indicating that the status of the associated protocol, patient, form, and course is complete.

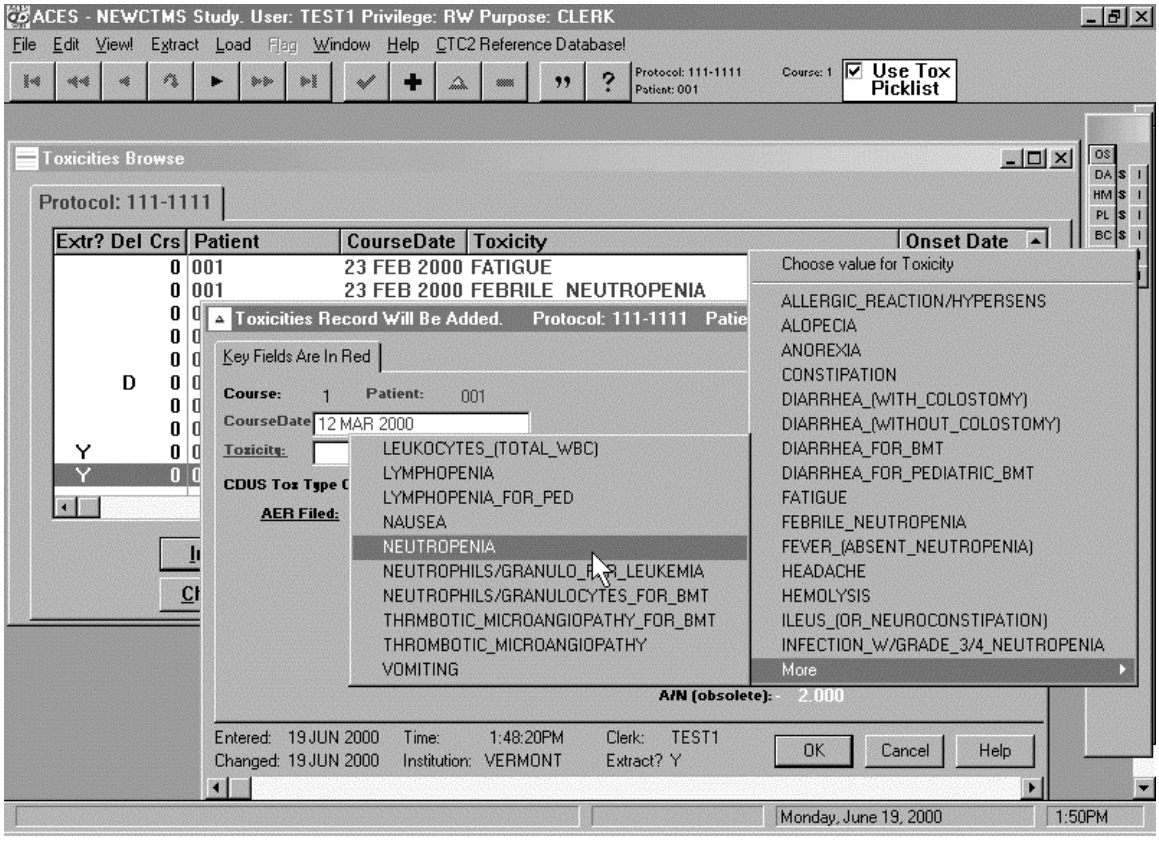
The BSA (Body Surface Area) is calculated by the program and displayed on the upper right portion of the window in the EN and CI forms. The formula used is:

BSA = ((Weight ^ 0.425) * (Height ^ 0.725) * 71.84) / 10000
(where Weight ^ 0.425 means Weight raised to the 0.425 power)

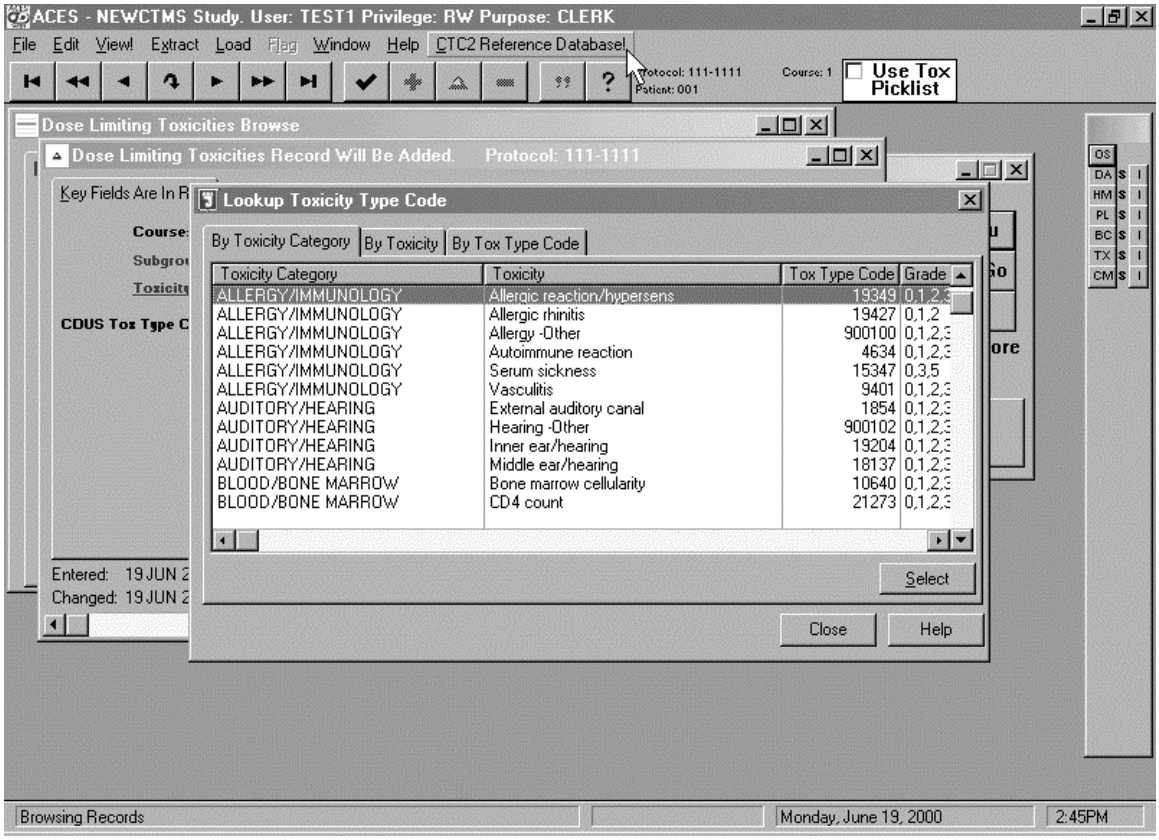
If the BSA is to be calculated differently for a given study, please enter the value resulting from the appropriate formula.

TOXICITY LOOKUPS

The Toxicity (TX), Baseline Symptoms (BS), and Dose Limiting Toxicities (DT) forms each have a toxicity description key field with a picklist that may be turned on or off. A yellow box appears in the upper right corner of the screen, allowing a user to activate or deactivate the picklist. The yellow box and it's check will remain as long as a TX, BS, or DT browse window is open. The toxicity picklist contains typical adverse event descriptions, but is certainly not exhaustive.



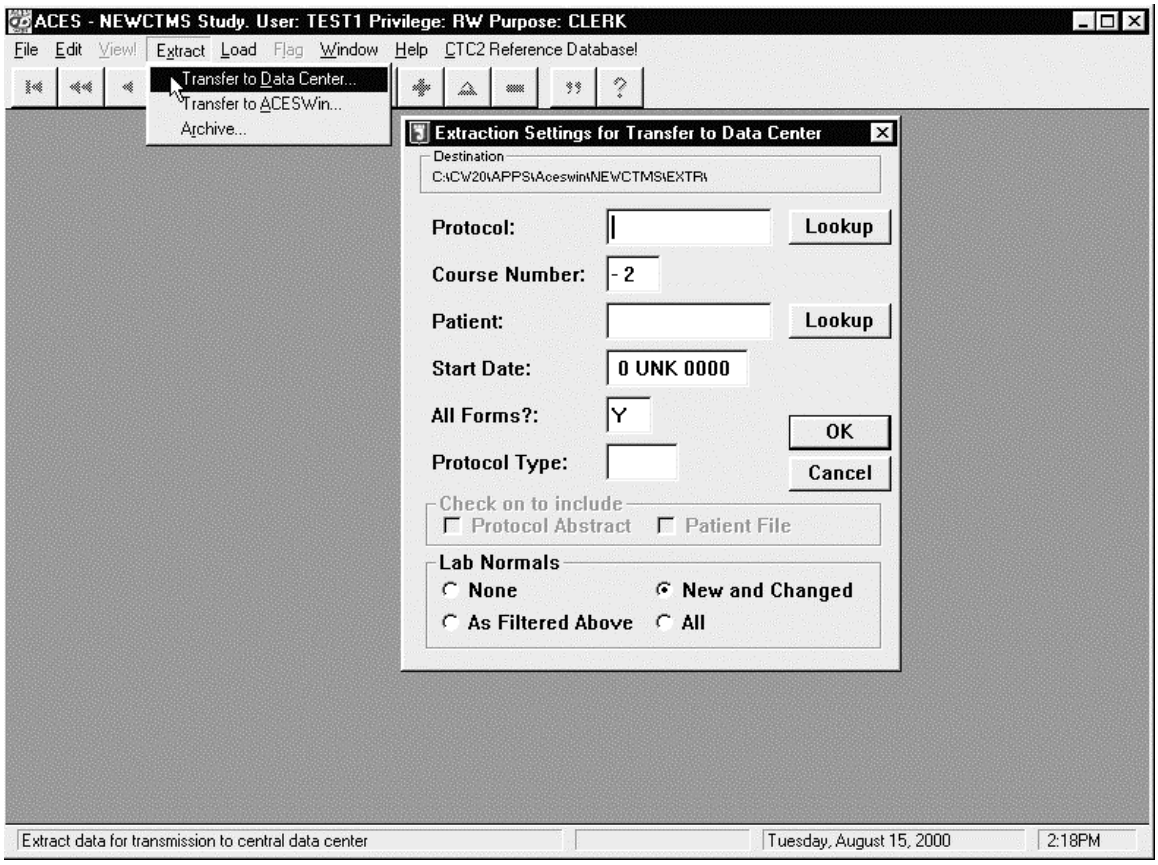
If the yellow Use Tox Picklist is turned on, choosing from the picklist will automatically fill in the CDUS Tox Type Code when that field is selected. The full CTC2 dictionary is available from within ACES® as a reference database. Using this CTC2 database enables a user to bypass the toxicity picklist described above. Clicking on "CTC2 Reference Database!" in the ACES® main menu bar brings up a browse window of CTC2 terms.



Selecting one of these records will always update the CDUS Tox Type Code. The picklist for the Grade field is based on the CDUS Tox Type Code (this picklist can be seen in the Grade column of the Lookup Toxicity Type Code window as displayed above). There are two ways that ACES® helps you to maintain consistency between the Toxicity (description) field and the CDUS Tox Type Code. First, the associated CTEP Toxicity description (second column in above window) is displayed in the upper center of the target form screen after choosing or entering a Tox Type Code. Second, if the form's Toxicity field is **blank**, the CTEP Toxicity description will fill it in. Thus, you can use the "CTC2 Reference Database!" lookup instead of the resident ACES® picklist for the Toxicity field. Use which ever interface works best for you. If you are updating an existing record and wish to have the "CTC2 Reference Database!" fill in the Toxicity field for you, simply blank it out before doing the lookup.

EXTRACTING DATA

Weekly, or as needed by the protocol, you can run the data extraction process. This process will scan through the database and make a copy of all data selected, for a variety of purposes. Data can be extracted to send to a central data center ("Transfer to Data Center"), to send to another ACES® installation ("Transfer to ACESWin"), or to archive it ("Archive").



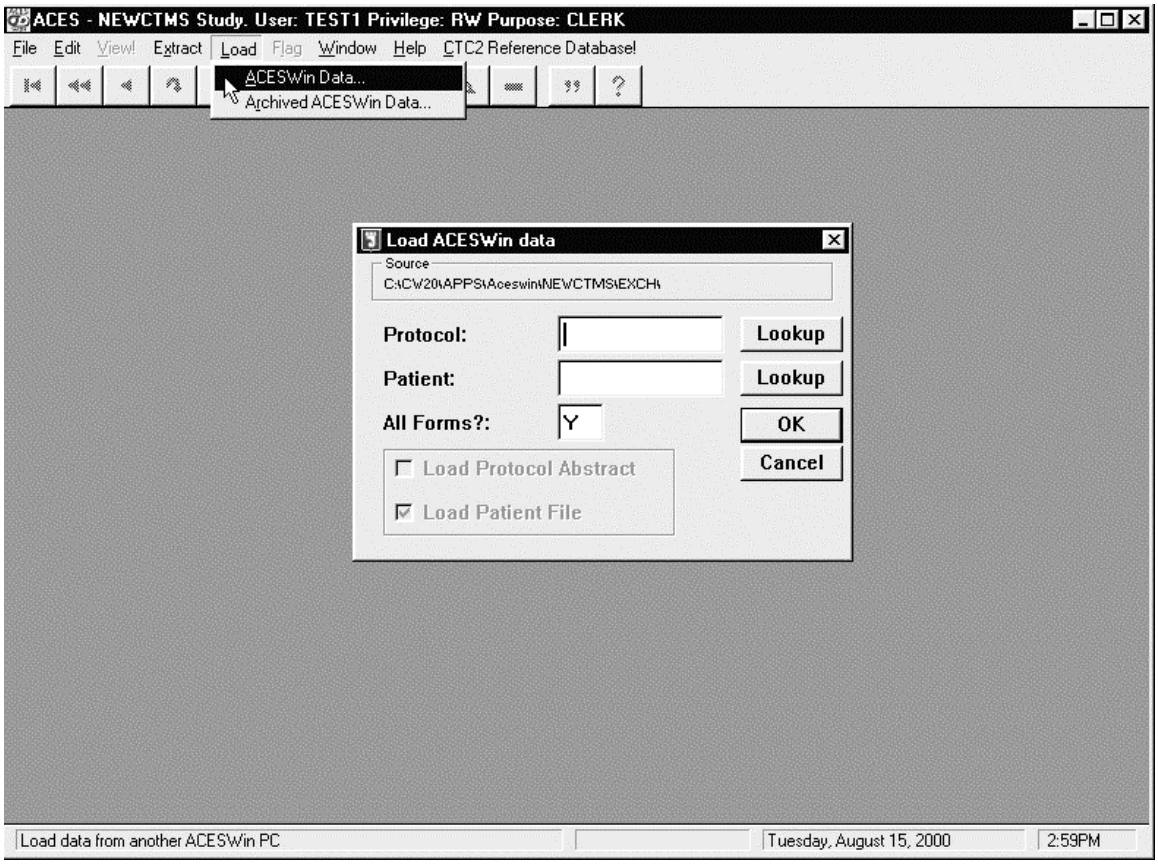
You may enter values into each of the displayed fields, in order to selectively filter your extract data. For example, to include all protocol 333-3333 data, enter that protocol (or run the Lookup function or press a mapped function key, if set in the Configuration Options menu, to select it). If you leave all other items in their default condition, then no other filters will be applied to the extraction data set. This would be the most common method of running a "Transfer to Data Center" since the system keeps track of which records have been added, changed, or flagged for deletion or undeletion since the last extraction. After a "Transfer to Data Center" extraction, each extracted record is flagged as "has been extracted", so that it will not need to be extracted again for this purpose. If for any reason a previously extracted record needs to be re-extracted, then entering a "Start Date" value equal to a date on or before the target record was last changed will force the system to re-extract all records added or modified on or after that date. Alternatively, if you just want to re-extract a few records, you can use the "Database" menu to edit each record, and save it with no changes. This will force the system to think these records need to be extracted, so that when the next "Transfer to Data Center" is run, those records will also be included.

Also note the “Destination” location specified at the top of the screen. This indicates the disk drive and directory where the extract files will be placed following the extract procedure. To change this location, run the Configuration Options procedure from the “File” menu.

However, for the “Transfer to ACESWin” or “Archive” functions, the system does not set the extraction flag and depends solely on the filter parameters you enter to decide which records should be extracted. Therefore, if you enter only protocol 333-3333 and run either of these procedures, then all 333-3333 data will be processed. If you enter a patient identifier, then all data for that patient will be extracted, etc. In addition, the “Archive” option will create a copy of the selected data, and, subsequently, delete it from the live database. Please use this option carefully. In the event that you do run it in error, you can use the “Load” function to re-load the archived data.

LOADING TRANSFERRED OR ARCHIVED DATA

If you, or another ACES® for Windows installation, has run a "Transfer to ACESWin" or an "Archive" procedure, then that data can be loaded, or re-loaded. Select the "Load" menu, followed by the "ACESWin Data" or "Archived ACESWin Data" options, depending on the method used to extract the source data. A window similar to the following will be displayed:



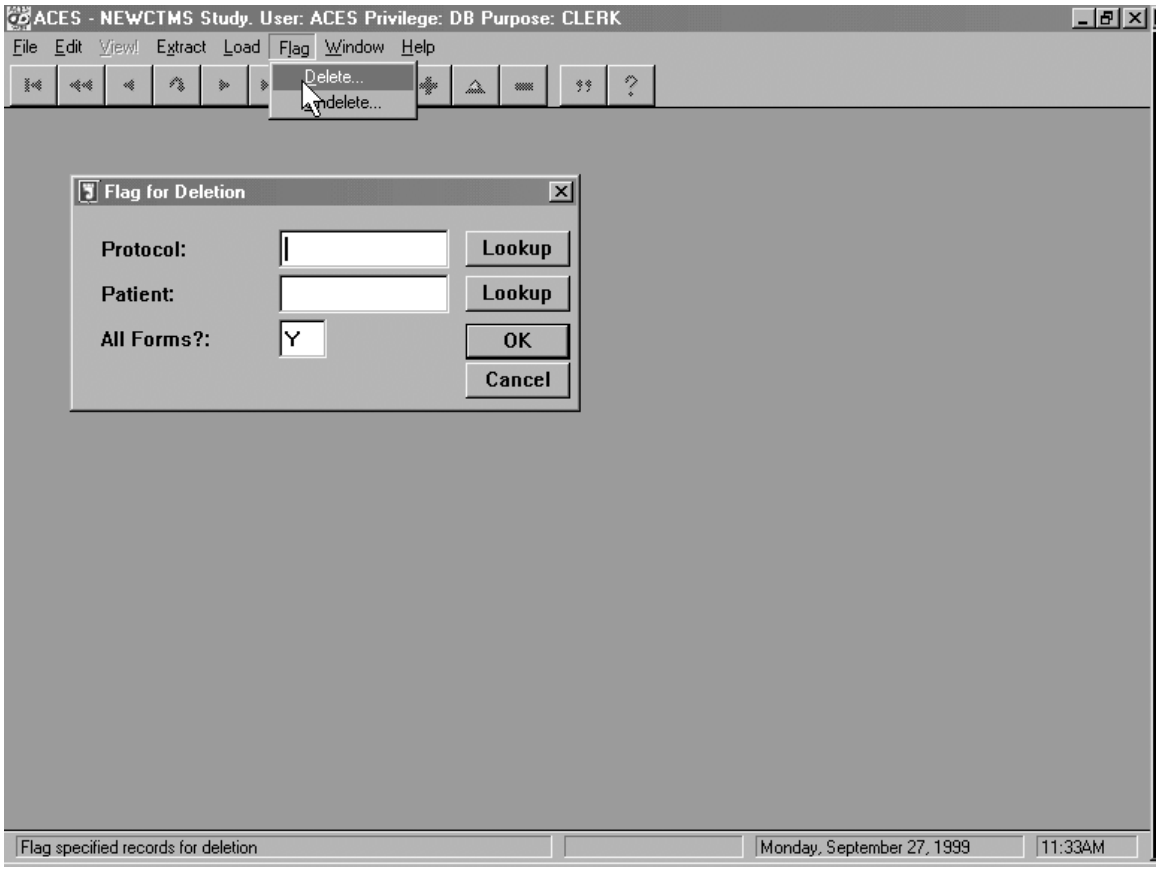
In general you will leave all filters in the default condition (missing) to load all data. Alternatively, you might choose to load only a single protocol, patient, or form. Note that when you load archived data, the system will not overwrite existing records. If you need to change the default destination, select "Configuration Options" from the "File" menu.

LOADING DATA FROM OTHER SYSTEMS

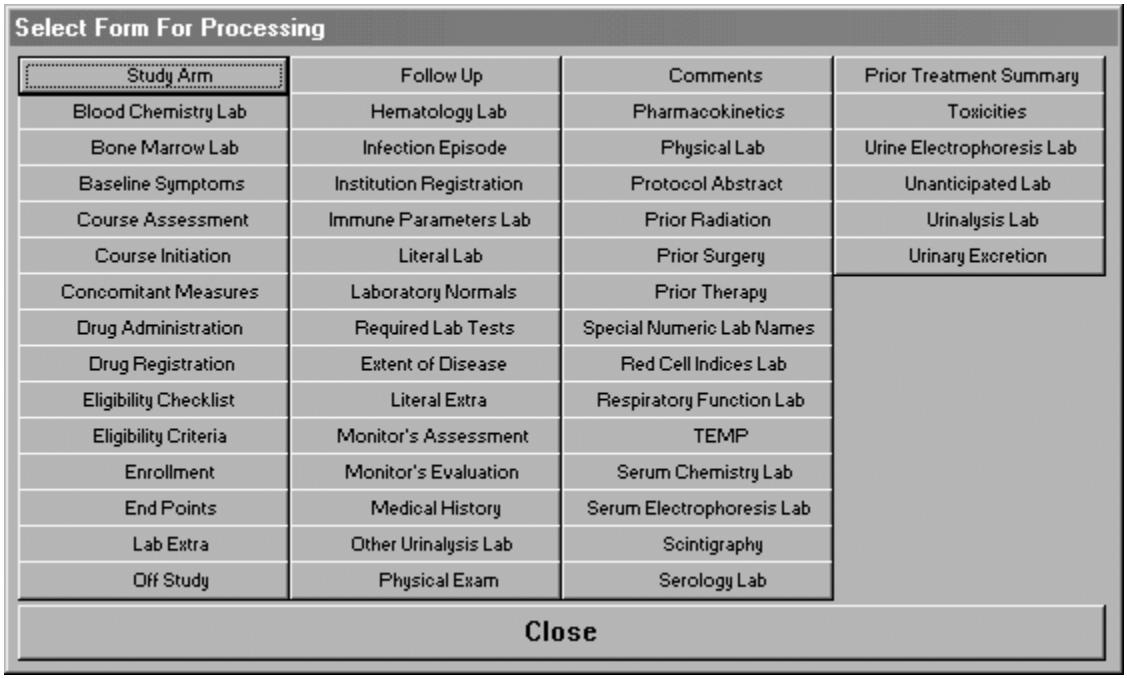
Your ASCII files need to be formatted as if they had been extracted from ACESWin. Run the Extract/Load File Structure report to get a printout of this format. If your system keeps track of the last changed time and you wish to load this into ACESWin with your data, make sure that it is formatted as hhmmss. Thus, 5:30:23 PM would be stored as 173023. If you do not keep track of the last changed time, set it to 0 in the ASCII file. The Alltime variable should also be set to 0.

GLOBAL FLAGGING OF DATA

Global flagging of data is restricted to those users with DB privilege. In the event that you need to flag a large number of related records for deletion or undeletion, you may do so by selecting the "Flag" menu item, as follows:



Records may be flagged for deletion, but not physically erased. You can elect to process a whole protocol, an entire form for a particular protocol, an entire patient, or an entire form for a single patient. Otherwise, if you need to be more selective about which records are flagged, you'll need to use the "Database" option to flag each record separately. If you enter "N" in response to the "All Forms" prompt, a list of available forms will be displayed where you can select which to include in the flagging process. Simply click on each form you'd like processed, one at a time. The window would be similar to the following:


Select Form For Processing
Study Arm
Follow Up
Comments
Prior Treatment Summary
Blood Chemistry Lab
Hematology Lab
Pharmacokinetics
Toxicities
Bone Marrow Lab
Infection Episode
Physical Lab
Urine Electrophoresis Lab
Baseline Symptoms
Institution Registration
Protocol Abstract
Unanticipated Lab
Course Assessment
Immune Parameters Lab
Prior Radiation
Urinalysis Lab
Course Initiation
Literal Lab
Prior Surgery
Urinary Excretion
Concomitant Measures
Laboratory Normals
Prior Therapy
Drug Administration
Required Lab Tests
Special Numeric Lab Names
Drug Registration
Extent of Disease
Red Cell Indices Lab
Eligibility Checklist
Literal Extra
Respiratory Function Lab
Eligibility Criteria
Monitor's Assessment
TEMP
Enrollment
Monitor's Evaluation
Serum Chemistry Lab
End Points
Medical History
Serum Electrophoresis Lab
Lab Extra
Other Urinalysis Lab
Scintigraphy
Off Study
Physical Exam
Serology Lab
Close

SPECIAL EX AND LX CONSIDERATIONS

The EX (Lab Extra) and LX (Literal Extra) forms are protocol specific, and each may have up to 100 different associated panels or screens. For details on adding a new form, see ADDING NEW EX OR LX FORMS. If multiple panels are required, see MULTIPLE LAB/LITERAL EXTRA FORMS IN A GIVEN PROTOCOL.

ADDING NEW EX OR LX FORMS

Users with DB privilege may add additional EX and/or LX forms without having to add a typefile record. For these forms only, follow these instructions:

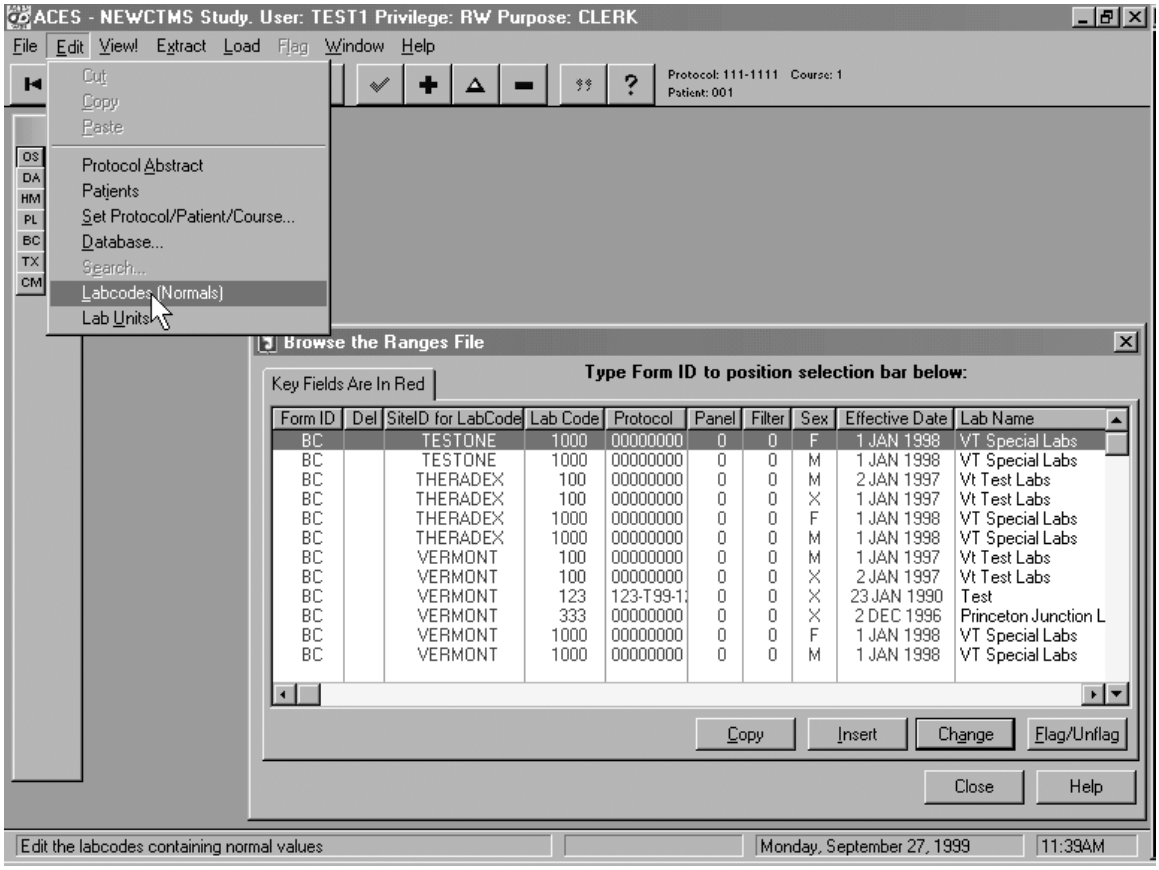
1. Insert a new or modify an existing Labels file record. Note that by updating an existing Labels record and changing the Protocol and/or the Panel fields will actually add a new record and leave the existing record unchanged. The structure of EX and LX must remain identical to the sample Labels records (protocol 333-3333). The one exception to this rule involves the number of fields. EX has room for up to 25 tests (along with the required "Significant?" flag fields). LX has room for up to 10 tests. In either case, your new form need not have the maximum number of tests.
2. Add Length file records for each label in the new Labels file record. This may be done by clicking on the "Update From Labels" button in the Length file Browse window. Length records will be added for each new label. You will have to update each of these new Length records with the proper lengths. See Length records for sample EX and LX labels for proper lengths.
3. A new labcode and associated units will need to be added to the Ranges file for a new EX form.

MULTIPLE LAB/LITERAL EXTRA FORMS IN A GIVEN PROTOCOL

Multiple Lab Extra or Literal Extra records in the Labels file for a given protocol are differentiated by a panel number. Only one record will exist in the Typefile for EX and another for LX for each protocol. When updating this record, ACES will ask for a panel number, used to display the associated labels. Since you have several sets of labels (each set associated with a panel number), it is important to pick the set with the greatest number. For example, suppose that in protocol 111-1111, panel 0 has 10 labels for non-key fields (SiteID for Labcode, Lab Code, Test 1, Significant?, Test 2, Significant?, Test 3, Significant?, Test 4, Significant?), and panel 1 has 14 labels for non-key fields (SiteID for Labcode, Lab Code, Test a, Significant?, Test b, Significant?, Test c, Significant?, Test d, Significant?, Test e, Significant?, Test f, Significant?).

ENTERING A NEW SET OF LABORATORY NORMAL RANGES

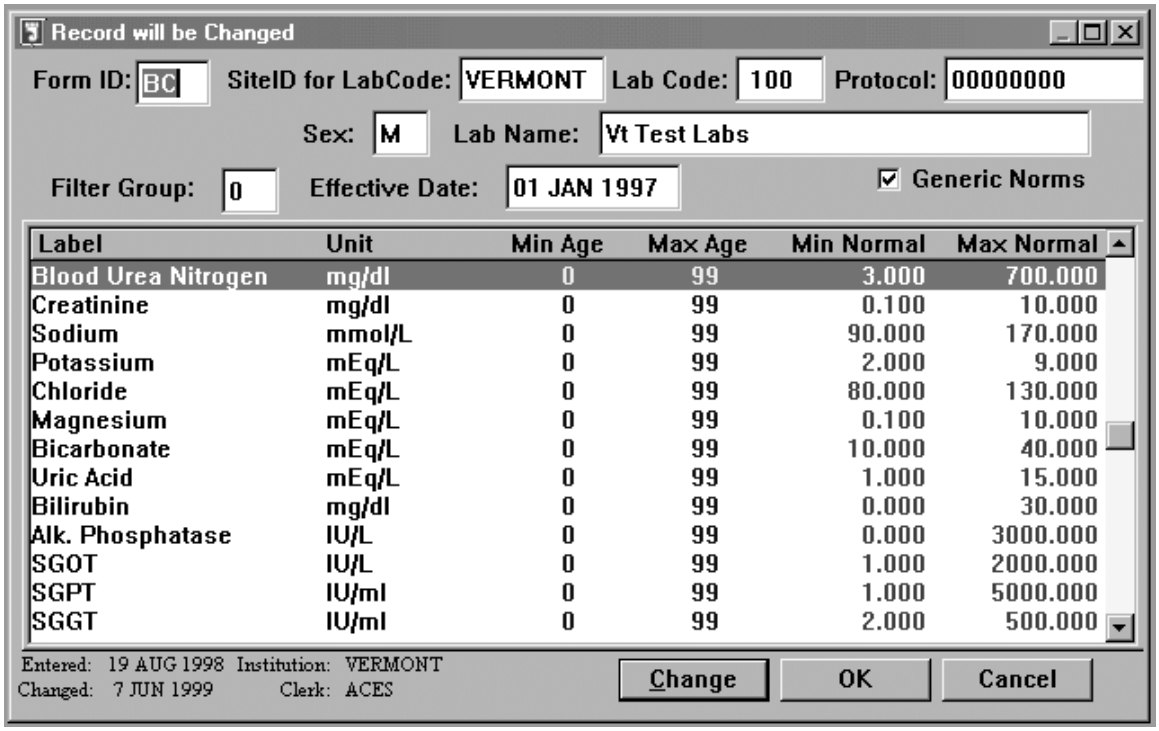
Lab normals need to be entered into the database when a new study starts, during the course of a study if a new lab is used, or when an existing lab updates any of its normal ranges. If you have received a Lab Startup diskette from the central data center, you may use that to load the ranges. However, after loading norms from a Startup diskette, you'll need to copy them so that your site ID is stamped on them, thus enabling you to make use of them for your own data entry. To enter them yourself, select the "Edit" menu, followed by the "Labcodes (Normals)" option. A sample browse window is shown below:



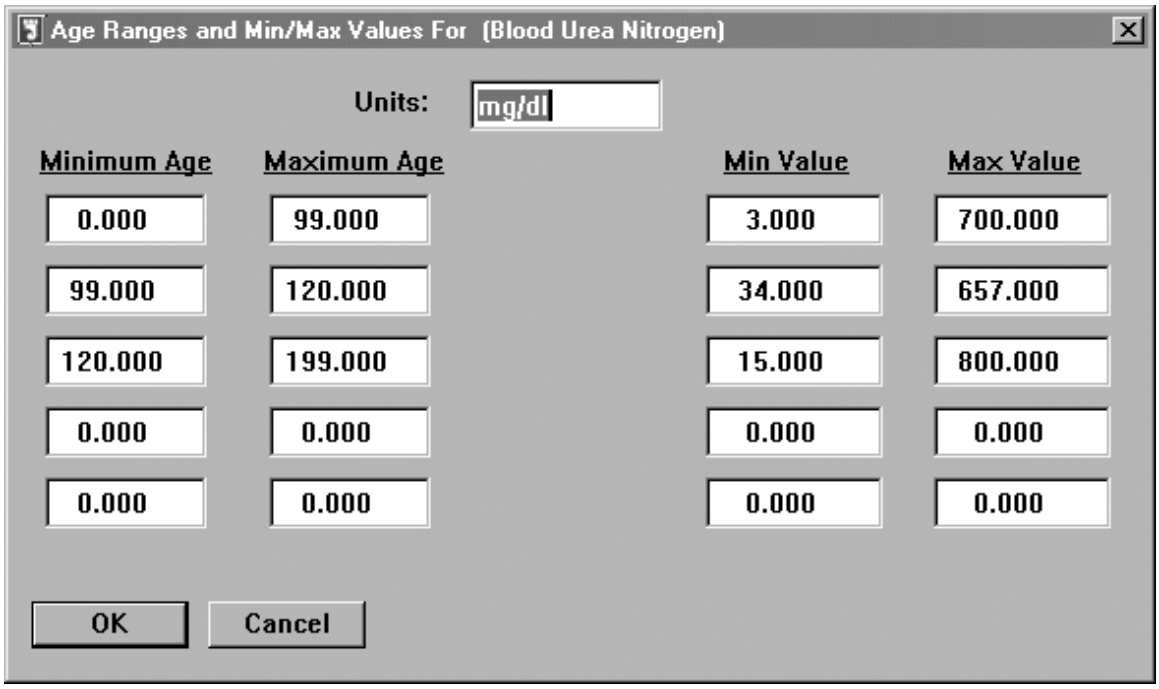
Click the "Insert" button to add a new record, or the "Change" button to alter an existing record. Click "Copy" to copy an existing set of normals to a new set. This option is useful if a new lab has ranges that are similar to an existing lab, or to make use of a set of normals that have been loaded from a Lab Startup diskette. Click the "Flag/Unflag" button to flag a record for deletion, or to undelete it. Due to the necessity of keeping an audit trail, and to maintain the integrity of older data, lab records cannot be erased, only flagged for deletion.

The first part of the entry form will display the overall characteristics of the lab, including lab name, gender, and code. The protocol number should only be entered for EX and any other lab form that is protocol specific. To set up a protocol specific form, see How To Design a New Study. All generic forms and their supporting structures utilize a protocol number of 00000000. The Filter Group field should be kept at 0 unless the patients are divided into two or more populations (like smokers vs non-smokers) having different lab norms. This field corresponds to the Filter Group field in the EN (Enrollment) form. The Generic Norms checkbox should only be checked when the laboratory's actual norms are not entered, but

instead general ranges are used. This allows for capture of the laboratory's name in each actual form, as well as general edit checking, without having to enter and/or keep updated the actual lab normals.

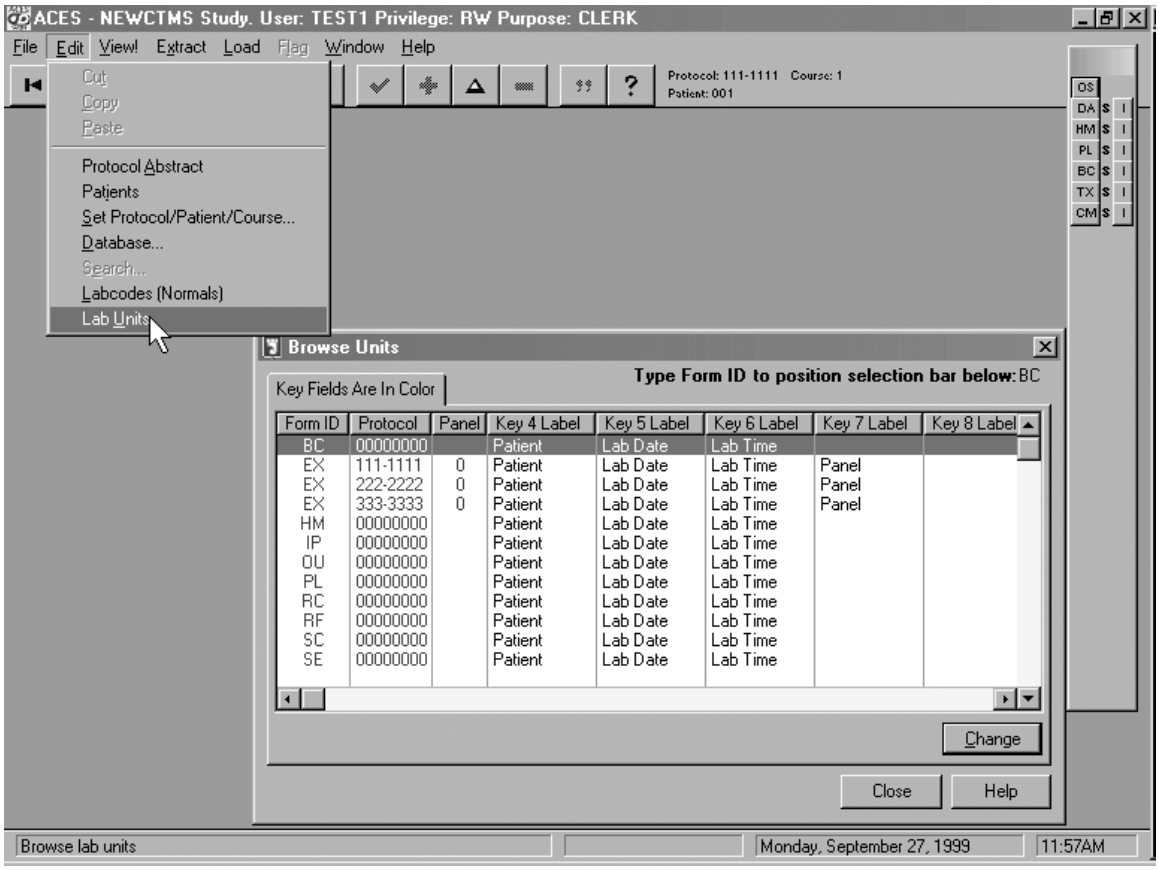


Double click (or highlight and click on the Change button) the lab test for which you wish to enter or update lab normals. You may enter up to five sets of age ranges and corresponding normals for each lab test. You will need to specify the units for the lab test. The units entered must be on the list of acceptable units. See Laboratory Units. The entry form will be similar to the following:

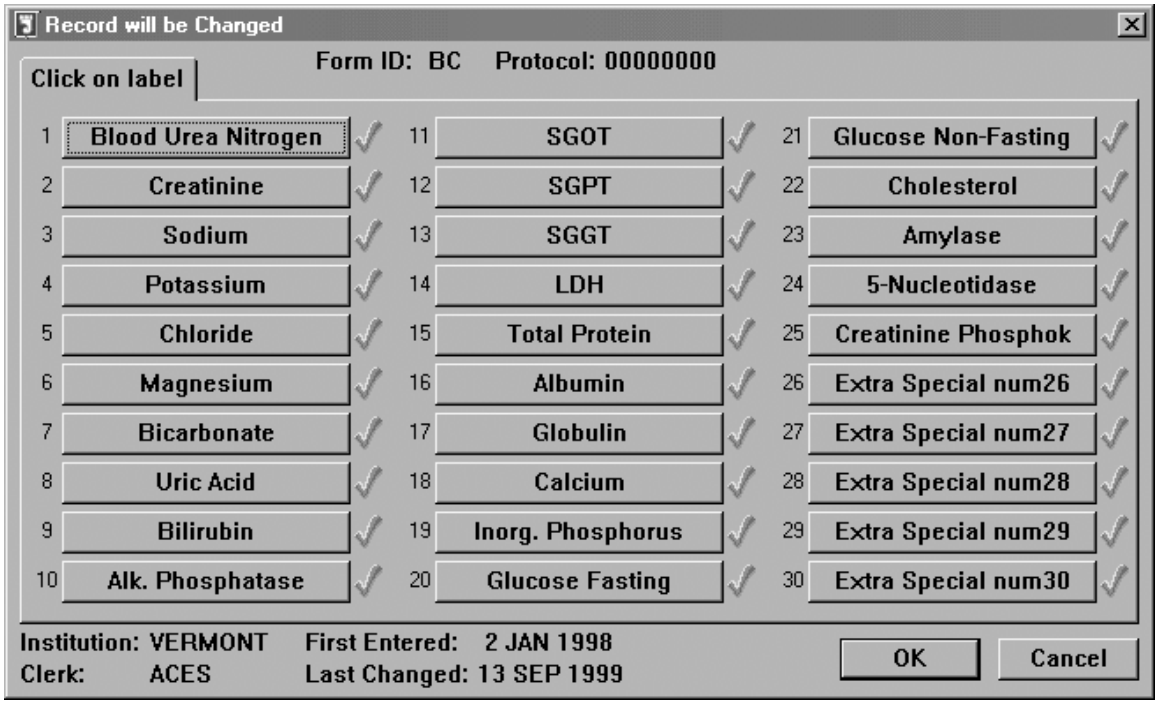


LABORATORY UNITS

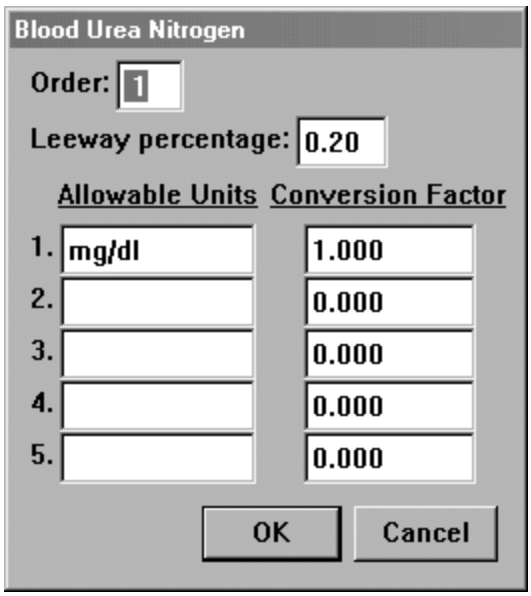
To aid in edit checking, ACES® keeps a database of the list of valid units that can be associated with each laboratory test. To modify this list, select the “Edit” menu item followed by the “Lab Units” option. Double-click (or highlight and click "Change") the selected lab form from the browse screen, which appears similar to the following:



Each lab test is displayed on a button with a small number to the left of it. The number indicates the sequence of the lab test on the actual form screen. To the right of each lab test button may be a green check mark. A check indicates that at least one unit has been stored for the associated lab test.



Clicking on each lab test button allows you to enter/update units and other associated data. For example, if BUN was selected to be altered from the Blood Chemistry file, the subsequent entry form would be similar to:



The order field enables you to re-order the display of lab forms, but not the data structure of the form. Thus, you may customize the tabbing order of the lab tests within each lab form to match the hard copy source documents you are entering data from. The Leeway percentage allows you to regulate how far above or

below a normal the patients values must go before an "Out of Range" warning window appears. The default value is 20%. You may enter up to five different valid units for each lab test. You may also associate a conversion factor to some “standard” unit that is used by your institution, or study. This conversion factor is used in order to merge laboratory results across different units.

LABORATORY NORMAL EXTRACT/EXPORT FILE STRUCTURE

Below is the general file structure generated when the Laboratory Normal Ranges file is extracted or exported. Note that there are several arrays in this structure. The actual normals are stored in a two dimensional array along with associated age ranges. The format of the array is 30 by 5 by 4. Each storage location is nine characters long, thus 30*5*4 = 600 nine character strings. Here is the logic behind the structure:

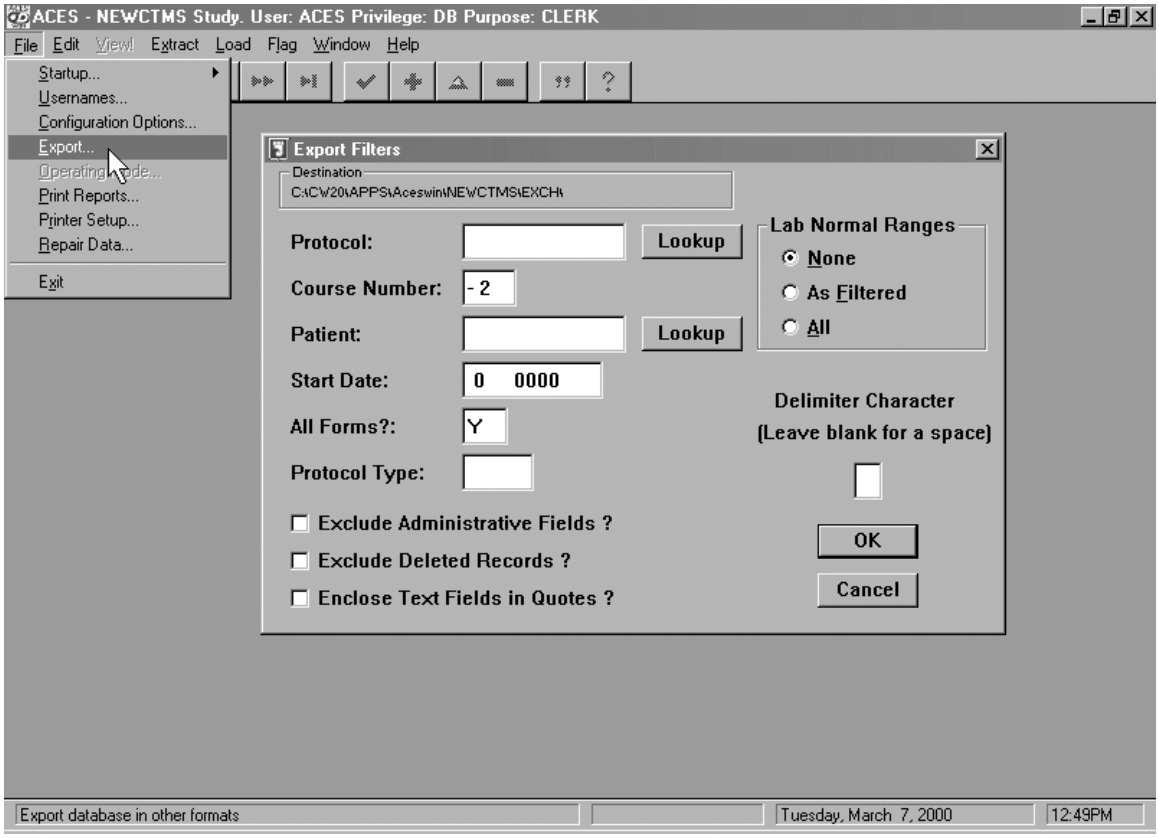
- maximum of 30 possible lab tests in each lab form
- maximum of 5 possible age ranges for each lab test
- for each age range, there are four values
    - Minimum age
    - Maximum age
    - Minimum normal limit
    - Maximum normal limit

The first 5*4*9 = 180 characters will be for the first lab test in the lab form that the lab norm (labcode) is for. In most cases, there will only be one age range for each lab test. This means that the first 4*9 = 36 characters of each "180 character block" will contain the min age, max age, min norm, and max norm, and the other 144 characters will be blank. When you use the export process and choose a delimiter, each field of course will be sectioned off with the delimiter.

FileID	STRING(3)	!This will always be ‘RA ‘
Version	STRING(4)	!ACESWin version
EXDTE	STRING(8)	!Date of last extraction
Clerk	STRING(8)	!Data entry username
EDTE	STRING(8)	!First entered date
CDTE	STRING(8)	!Last changed date
CTime	STRING(7)	!Unused in Ranges
DelFlag	STRING(1)	!Deactivates record if set to 'D'
DelDate	STRING(8)	!Date deleted status last changes
Protocol	STRING(12)	!Protocol number for protocol specific ranges
Institution	STRING(8)	!Site where record was last changed
RecType	STRING(3)	!Lab form ID (e.g., HM = Hematology)
LabSite	STRING(8)	!Originating institution of labcode
LabCode	STRING(4)	!Numeric code for laboratory
Panel	STRING(2)	!A particular Lab Extra screen
GenFil	STRING(1)	!Generic filter from the EN (Enrollment) form
Sex	STRING(1)	!Sex of labcode (X, F, or M)
EffectiveDate	STRING(8)	!Date lab code is first effective
GenericLabNorms	STRING(1)	
LabName	STRING(32)	!Name of the laboratory
For T = 1 to 30		!30 possible tests
For R = 1 to 5		!Each test has 5 age ranges, some unused
MinimumAge(T,R)	STRING(9)	
MaximumAge(T,R)	STRING(9)	
MinNormal(T,R)	STRING(9)	
MaxNormal(T,R)	STRING(9)	
End		
End		
For T = 1 to 30		!30 possible tests
Units(T)	STRING(10)	!Chosen units for test
End		
For T = 1 to 30		!30 possible tests
Factor(T)	STRING(8)	!Conversion factor to default unit
End		
Send	STRING(1)	!Marks record for sending

EXPORT DATA

To export data from ACES® for Windows into a standard ASCII file format, you select the Export option from the main File menu. You should verify in the Configuration Options item from the File menu that the target location for your export files is correct. The "Remote Transfer and Load" specification will be used as the export location. The Export option is selected in the example below:



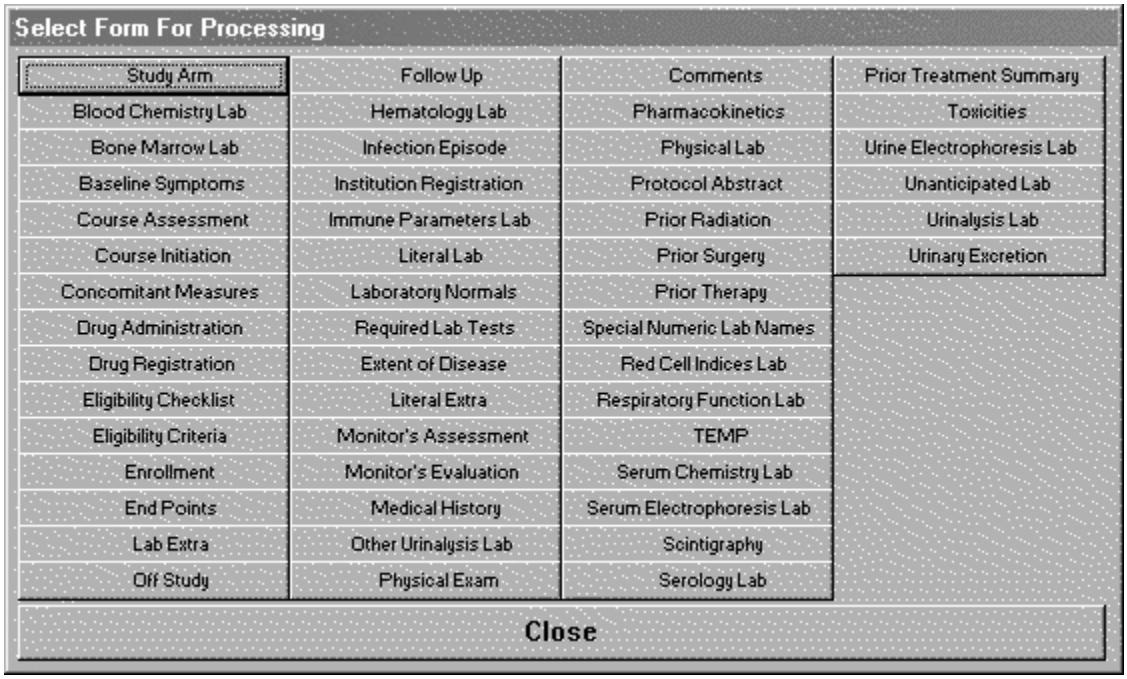
Subsequently, the export filter window is displayed which allows you to select which subset of data you'd like exported. You may restrict output based on Protocol, Patient identifier, Course, Protocol Type, Form Type, and Start Date. Start Date refers to the latest date that a form was entered or changed. For example, if you'd like to include all data entered or changed since January 1, 1998, you would enter 01 JAN 1998 into the Start Date field. If you specify "N" for "All Forms ?" you will, upon completion of the filter window, be able to select which forms to export.

In addition, you'll need to specify how you'd like the output ASCII file to be formatted. If you'd like the fields separated by a character, enter that character (e.g. a comma) into the Delimiter field. If you do enter a value here, then the first record in each output data file will contain the field labels for each field extracted. This option often simplifies the process of importing the data into other programs. If you do not specify a delimiter, then a space will separate fields and no field labels will be included in the first record.

You may also elect to include or exclude lab normal ranges, deleted records and administrative fields. Due to audit trail logic, all records entered are saved in the database. Deleted records are flagged with a "D" in the delete flag field. Administrative fields include information for the first entered date, last changed date, last changed time, last entry clerk user identifier, institution code, last deletion date, delete flag, last extracted date, overall last changed date and overall last changed time.

Finally, you may decide whether to enclose literal fields in quotes. This option will be dependent on the target software that will be importing your data. If you select this, the field labels will also be enclosed in quotes.

Following the filter selections, if you have entered a “N” to export “All Forms” then a form selection screen will be displayed. Click the desired form. A sample such form would be similar to the following:



At this point the export process will begin and informational messages will be displayed as each form selected is processed. The target location for the export files is identified in the Configuration Options item located in the File menu.

HOW TO DESIGN A NEW STUDY

When designing a new study containing non-standard forms, it is recommended that the study's structural details be kept isolated from test data.

- Setup a new subdirectory of ACESWin for the new study.
- The subdirectory should then be filled with the following seven subdirectories: Data, Atrl, Arc, Exch, Extr, Bkup, and Bknorms. All of these should be empty except for the Data directory.
- The following files should be copied into the Data subdirectory from another Data directory (an existing study or by installing fresh data files from the installation diskettes into a temporary directory): EXVL.TPS, HOT.TPS, IDFORM.TPS, KEYPOS.TPS, LABELS.TPS, LENGTH.TPS, MASTER.TPS, TYPEFILE.TPS, IMTTOX.TPS, and possibly LIST.TPS (copy this file in only if you want to use the picklists from some existing study).
- Enter Protocol Abstract record, including the eligibility checklist questions.
- Design database structure in ACESWin as described in the pages that follow. Create Sequence records for baseline and all anticipated courses (or cycles). For testing purposes, you may want to setup another ACESWin subdirectory. The data structure is stored in IDFORM.TPS, KEYPOS.TPS, LABELS.TPS, LENGTH.TPS, TYPEFILE.TPS, and LIST.TPS. These files may be copied into the testing Data directory from the development Data directory. The PA.TPS (Protocol Abstract) and SEQUENCE.TPS files should also be copied when they are altered. Note that you MUST keep a copy of the Sequence file with no test patients.
- If your structure needs to be distributed to other sites, choose the MakeDisk option in the Startup submenu of the File menu.

Setting up studies with non-standard forms may require the implementation of each of the below steps. If a new study utilizes existing forms, then steps 2, 4 and possibly 10 may be all that is necessary.

1. Database Structure Details
2. Adding Protocol Abstract information
3. Selecting which forms and form identifiers to use
4. Choosing what forms should be completed for each protocol and course
5. Defining field labels and edit checks
6. Special picklist codes
7. Editing field types
8. Assigning field lengths
9. Modifying the Form Display
10. Defining Protocol Specific Lab Forms

DATABASE STRUCTURE DETAILS

If designing a study that uses completely new files, the following requirements must be met:

- The CI file must be included in the database with at least the fields specified below.
- The EN file must be included in the database with at least the fields specified below ONLY if lab files will be present in the database that use labcodes.
- The fixed elements of the key structure are the Form ID and the Protocol number. **All patient specific forms must have the patient identifier in the Key 4 slot.**

- Forms containing a memo field must conform precisely to the structure of PH.

- The key fields have the following length and type limitations (true for version 4.04, may be expanded in future versions):

Field	Length	Types
Key 4	12	string
Key 5	33	integer, string, date, character
Key 6	33	integer, string, date, time
Key 7	8	integer, string, date, time, character
Key 8	8	integer, string, date
Key 9	5	integer, time

If designing a study that uses some or all elements of the standard database, the fields listed below must remain in the order specified. The safest policy to adhere to when using these standard forms, is to use them only when adding new fields to the end of the existing form. If you wish to delete fields or add new fields in the middle of the form, please create a new form.

File: EN

Sex	Non-key field 1
Birthdate	Non-key field 4
Registration date	Non-key field 5
Age	Non-key field 6
Weight	Non-key field 7
Weight Units	Non-key field 8
Height	Non-key field 9
Height Units	Non-key field 10
Filter Group	Non-key field 11

File: CI

Weight	Non-key field 3
Weight Units	Non-key field 4
Height	Non-key field 5
Height Units	Non-key field 6

File: CI & CA

Startdate	key 5

Files: EX & LX

Panel	Key 7

Files: All labs with a labcode

Labdate	Key 5
SiteID for Labcode	Non-key field 1
Labcode	Non-key field 2
Significant?	Non-key fields 4,6,8,...

File: **TX**

Course Date	Key 5

File: **PE**

Non-key fields 1,4,7,10,13,16,19,22,25,28,31 provide program control.

Files: **TX & BS**

Toxicity	Key 6
CDUS Tox Type Code	Non-key field 1

Files: **DT**

Toxicity	Key 5
CDUS Tox Type Code	Non-key field 1

File: **EC**

Checklist Number	Non-key field 1
Checklist questions	Non-key fields 2 through 41
Eligible?	Non-key field 42

Note that the picklist for the second non-key field is used for all other fields except Patient, Checklist number, Patient Eligible?, Why Not?, and Waiver number. If additional fields are added, this picklist (if any) will be applied to them.

Files: **CM, PT, PR, PS**

All key fields

Files: **PH**

All fields

File: **UL**

Value Type	Non-key field 4
Numeric Value	Non-key field 5
Literal Value	Non-key field 6
Literal Continued	Non-key field 7

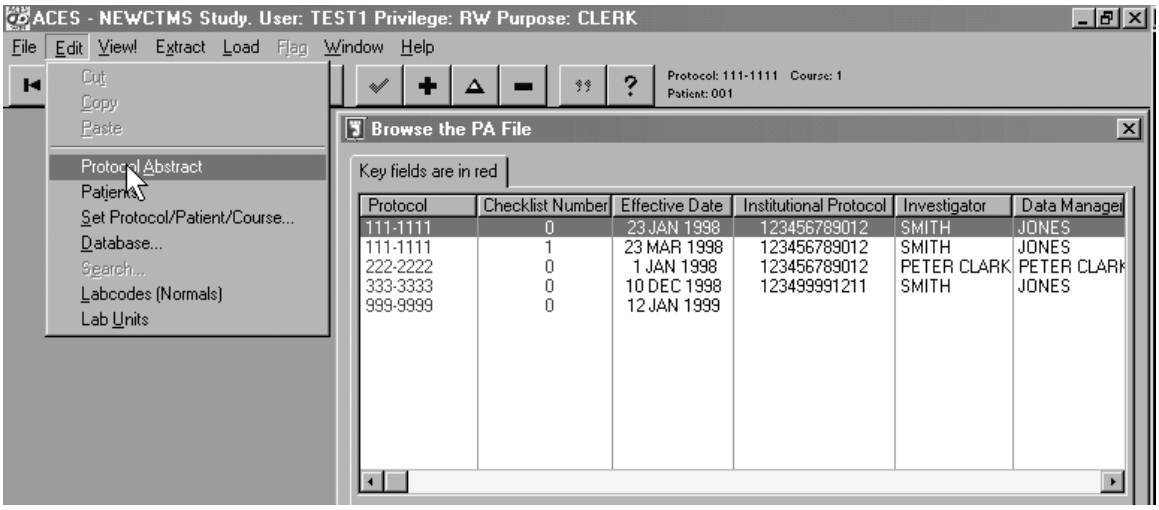
File: **DA**

This field may be changed without any consequences. It is primed from the previous DA record on inserts after the first insert. This special quality is lost if its name is changed or if it is moved to a different position in the file structure.

Lot Number	Non-key field 1

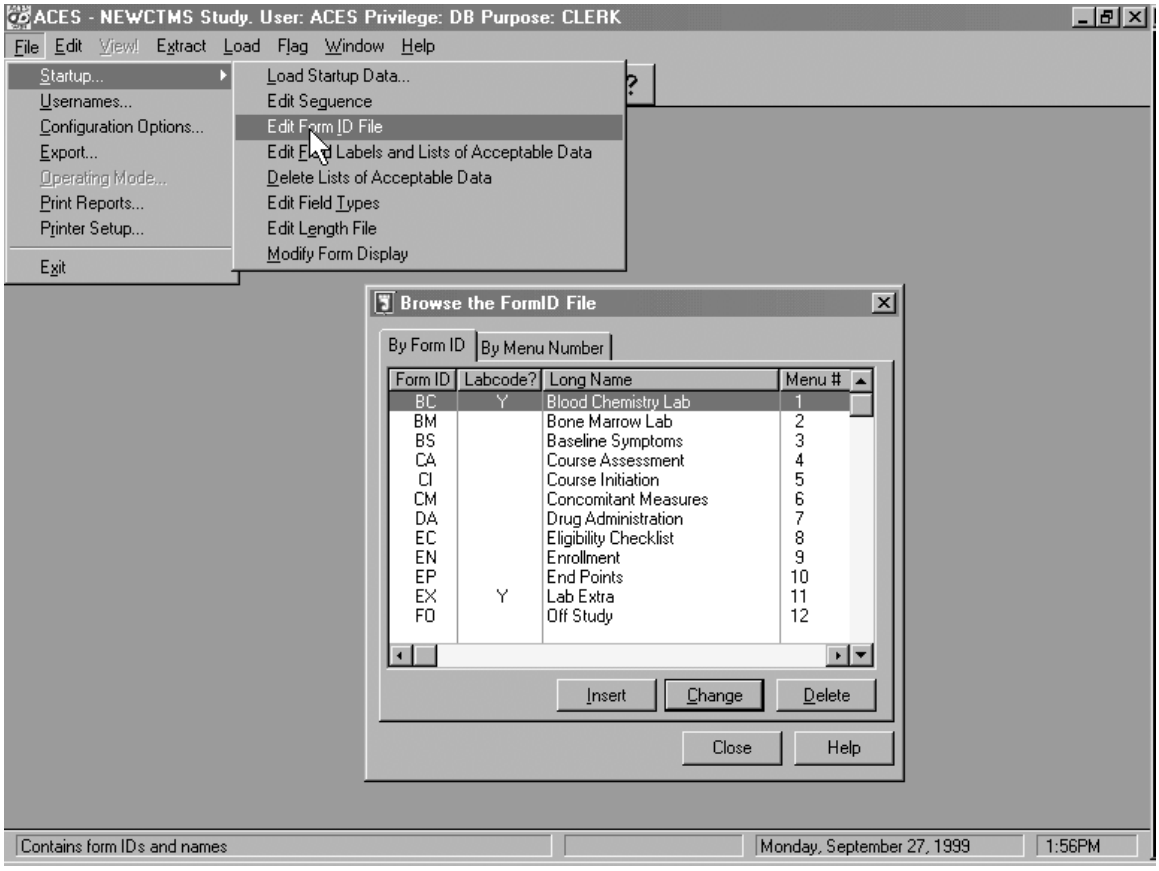
ENTERING A PROTOCOL ABSTRACT

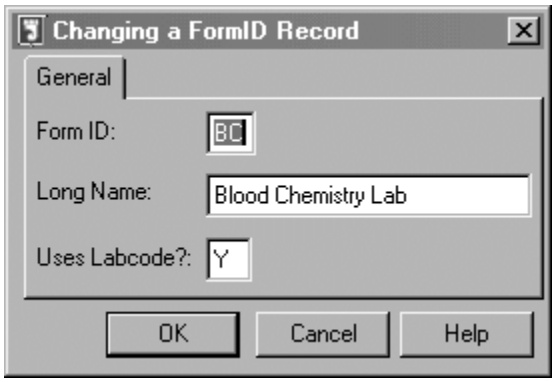
To enter your own Protocol Abstract information, select the "Edit" menu and the "Protocol Abstract" option. Once in the Browse screen, click the "Insert" button to add a new record. In order to enter data for a particular protocol, a record must exist in the Protocol Abstract file that corresponds to the desired protocol identifier. In addition to the protocol identifier, there are various other fields available for entry. In particular, you may enter one set of eligibility questions for each protocol and version (if there are amendments to the original protocol). A sample browse window is shown below:



CHOOSING FORM IDENTIFIERS AND NAMES

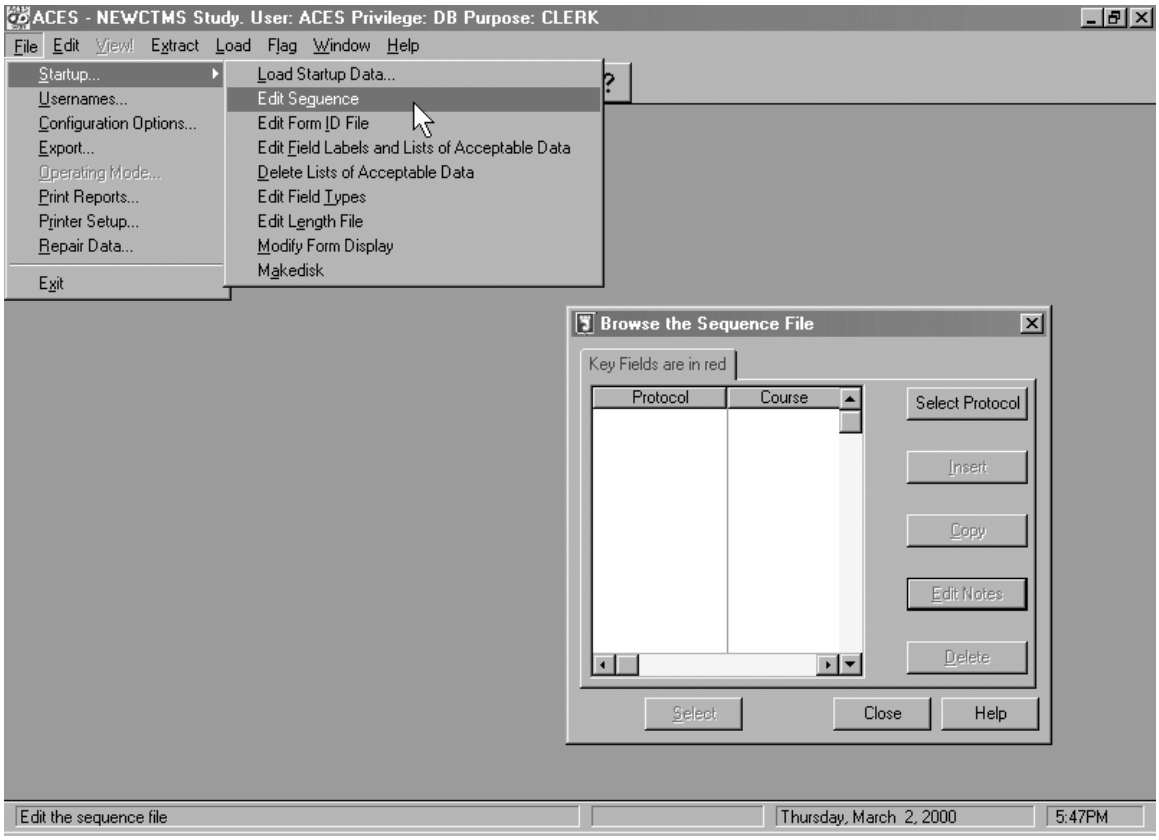
From the "File" menu, select the "Startup" option, followed by the "Edit Form ID File" procedure. This will allow you to enter an identifier and associated long name for each electronic form to be used for a study. Each form should also be flagged in terms of whether Labcode field logic will need to be used, i.e. only for forms where we need to collect information associating the lab results with the lab that processed them. Below is a sample browse and an associated BC (blood chemistry) FormID entry form. Note that the "Menu#" associated with each Form ID will be assigned in alphabetical order after each new form is first selected for entry from the "Database" menu item.

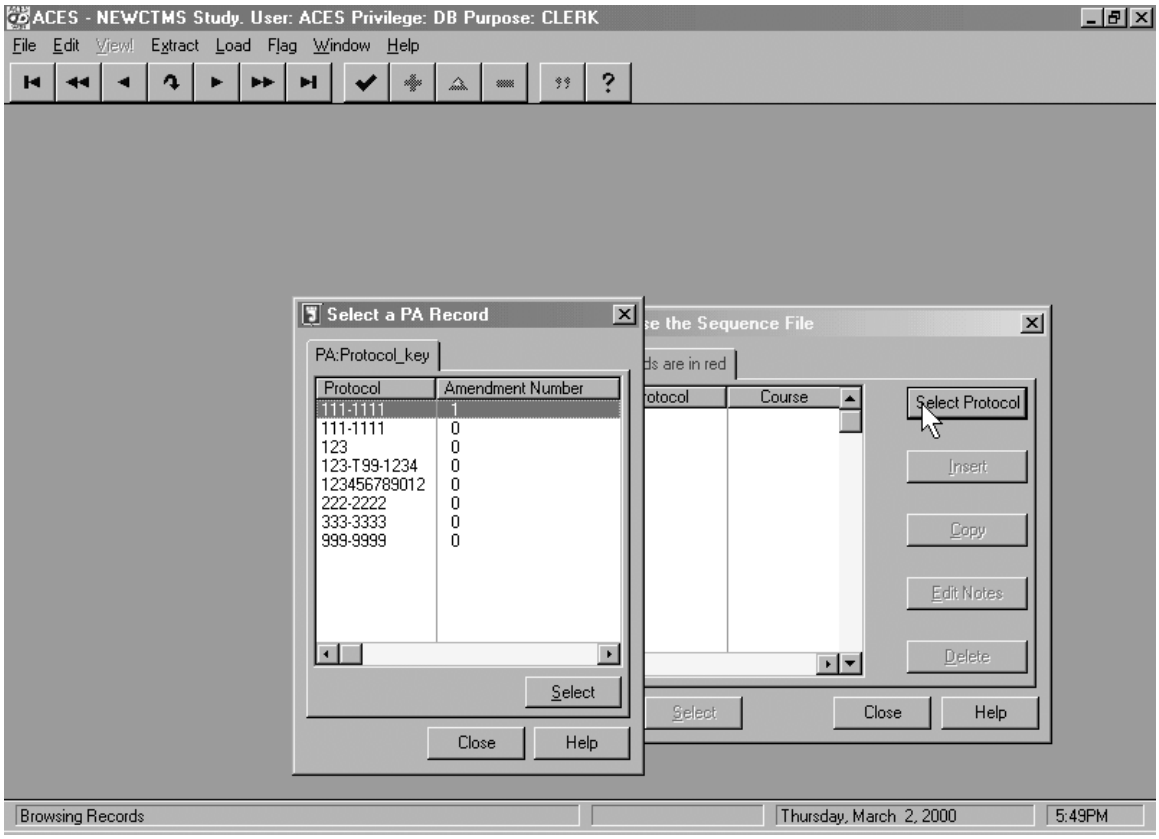


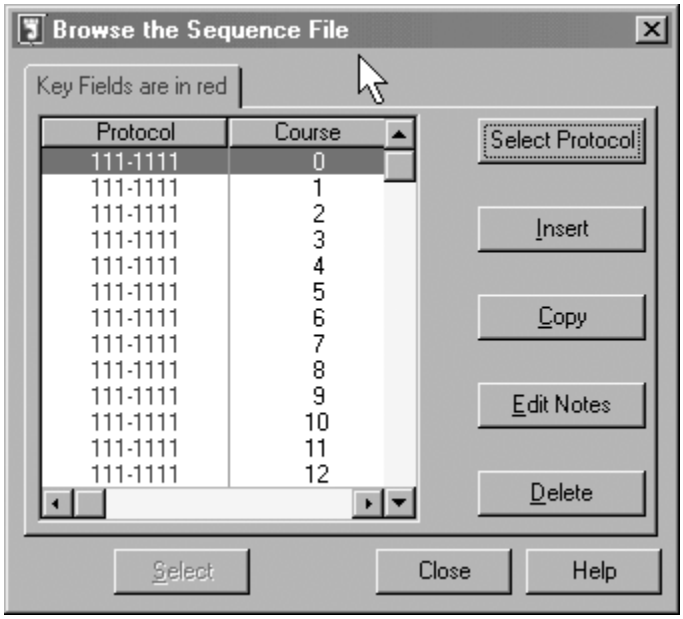


CHOOSE FORMS REQUIRED FOR EACH COURSE

The sequence bar provides an online reminder regarding which electronic forms need to be completed for each course or cycle. This is strictly a user guide; it does not prevent the completion of forms not listed for a given course. To insert data into the Sequence file, select the "Startup" option from the "File" menu. Then, select the “Edit Sequence” procedure. This Sequence file needs to have information added for each protocol, including which forms need to be filled out for each course, and (optionally) associated notes. The browse window displays the Protocol and Course fields. First, select a protocol from the Protocol Abstract file by clicking on the Select Protocol button. Then, select a record to edit or copy, or click “Insert” to add a new record. Sample screens are displayed below:



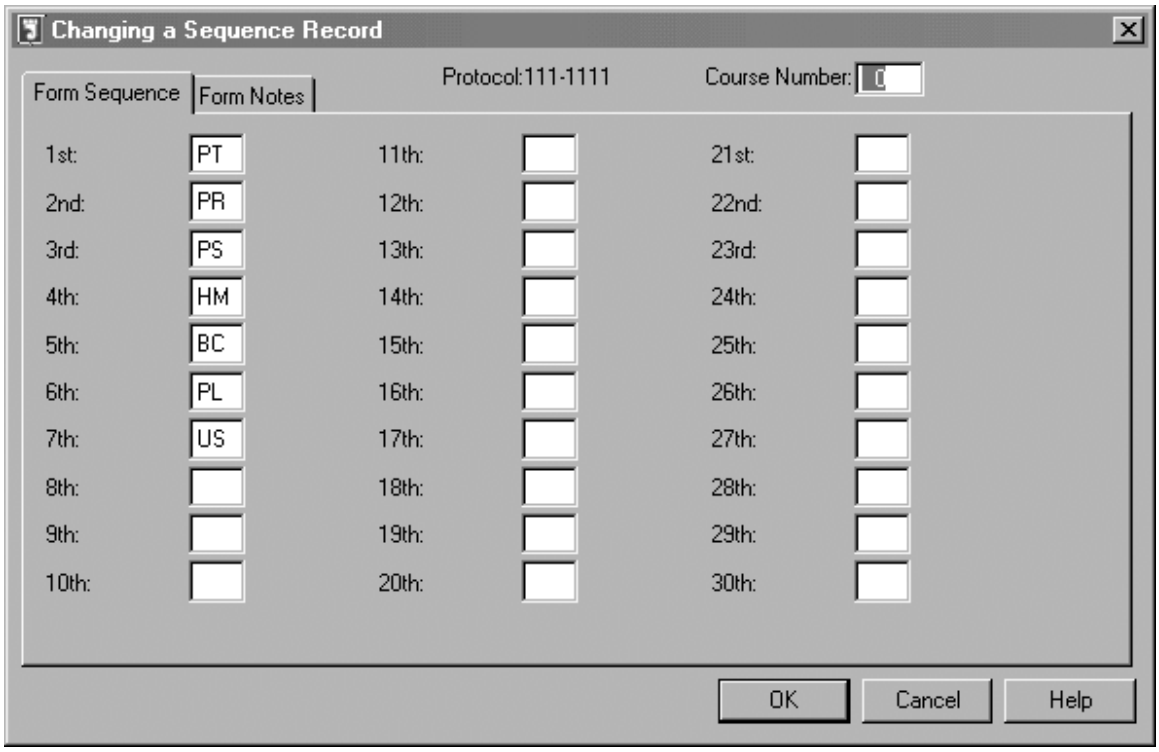




Once in the entry form, you may modify a record's contents, or add notes related to each electronic case report form. **WARNING: Form notes may be altered throughout a study. However, the form sequence may only be altered during the initial record insert.** Since the Sequence file is driven by the protocol, course and patient numbers, forms that are NOT patient oriented should not be included in the sequence of forms to be filled out. For example, the DT (Dose Limiting Toxicities) and EP (End Points) forms as they are currently defined should not be included in a Sequence record.

When a patient is added to the Patient file, the Sequence file automatically creates a record for that patient for each course. These automatically generated Sequence records cannot be deleted. This is why it is important to always keep a copy of the Sequence file separate from test or live clinical data. This Sequence file can be updated throughout the study to include new form notes or whole new courses. Using the MakeDisk facility, the updated Sequence file can be correctly extracted. The extracted Sequence file is then loaded into the live database ACESWin using the Load Startup Data option in the Startup submenu of the File menu. This loading process will correctly insert new Sequence records for existing patients.

The sample entry form below shows that for protocol 111-1111 and course 0, we expect information for the PT (prior therapy), PR (prior radiation), PS (prior surgery), HM (hematology), BC (blood chemistry), PL (physical labs), and US (urinalysis) forms.



DEFINE LABELS AND EDIT CHECKS

From the “File” menu, select the “Startup” option, followed by the “Edit Field Labels and Lists of Acceptable Data” procedure. You can insert and change information related to field names and associated edit checks for these fields. Records stamped with the 00000000 protocol cannot be deleted. If you wish to add a form for a particular study, use the study's protocol number instead of 00000000. This may be deleted later if desired. If you wish to add a form that you intend on using for several studies, use the generic, default protocol 00000000. You must run the “Delete Lists of Acceptable Data” procedure , available in the Startup submenu of the File menu, to delete edit checks. You will need to identify key fields (those field values which serve to uniquely identify a record) and non-key fields. Each field may have an edit check designated as “R” (range of values) or “E” (list of acceptable entries, otherwise known as a picklist). Ranges are entered into “Min” and “Max” screen prompts, which appear if a field is selected that has an “R” edit check type. Fields with an “E” edit check type use the notation “R=Radiation,C=Chemotherapy”, for example, to enter the set of valid codes. There must be no spaces in this list, so you may want to use the

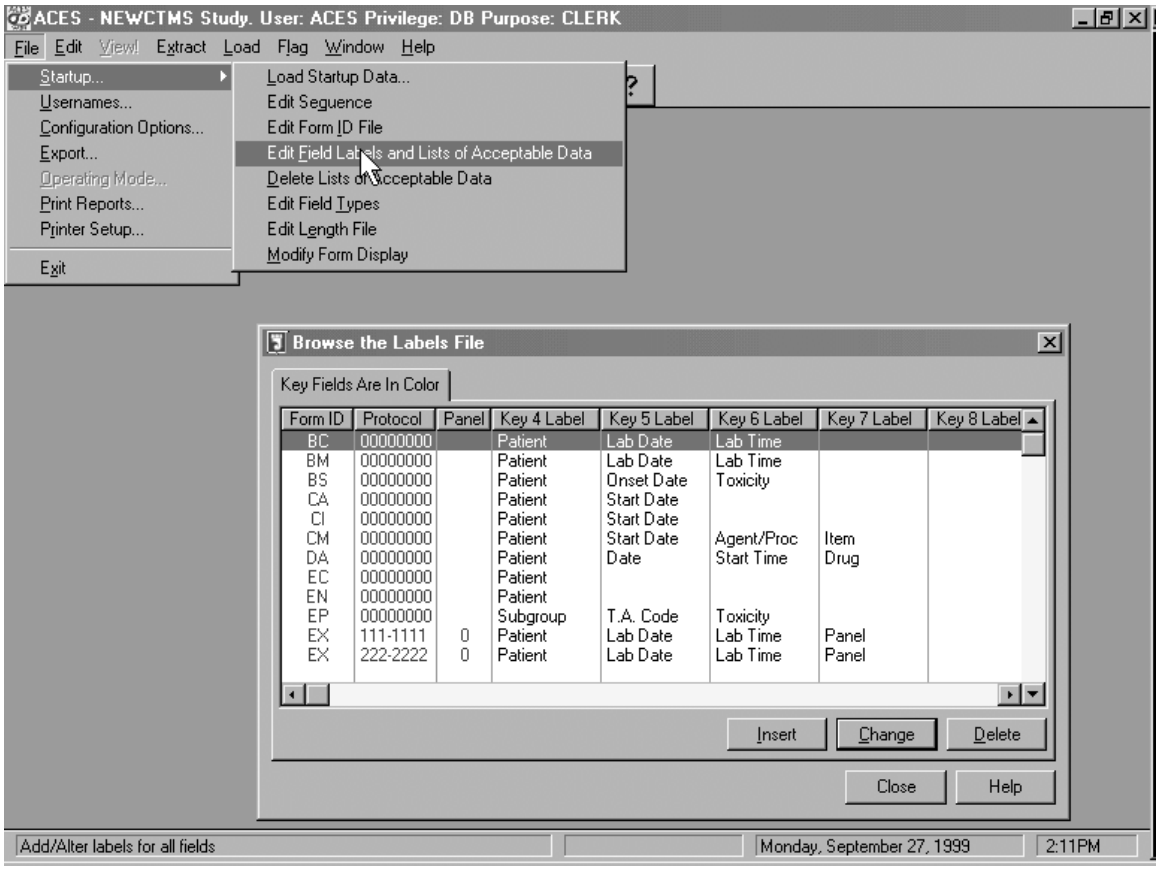
underscore character to separate words (e.g. 1=No,2=Life_Threatening). The equal sign and explanation are strictly optional, so Y,N,X=Unknown is a perfectly good picklist with three options. Pressing the F10 function key will display the picklist for the current field, if one exists. See “Special Picklist Codes” for more picklist details.

If a particular study will use the same form structure, but different edit checks, click on the Change button for the labels record having the identical structure. Next, change the Protocol from its current setting (usually 00000000) to the protocol number for the new study. Keep the labels the same and specify the edit checks required. Note that you will have to completely define your edit checks; the edit checks are keyed to the protocol number. When you click on the OK button, a new Labels record will be inserted, leaving the original one intact. It will not be necessary to add Types for these fields, but you will need to add field lengths. See "Assigning Field Lengths".

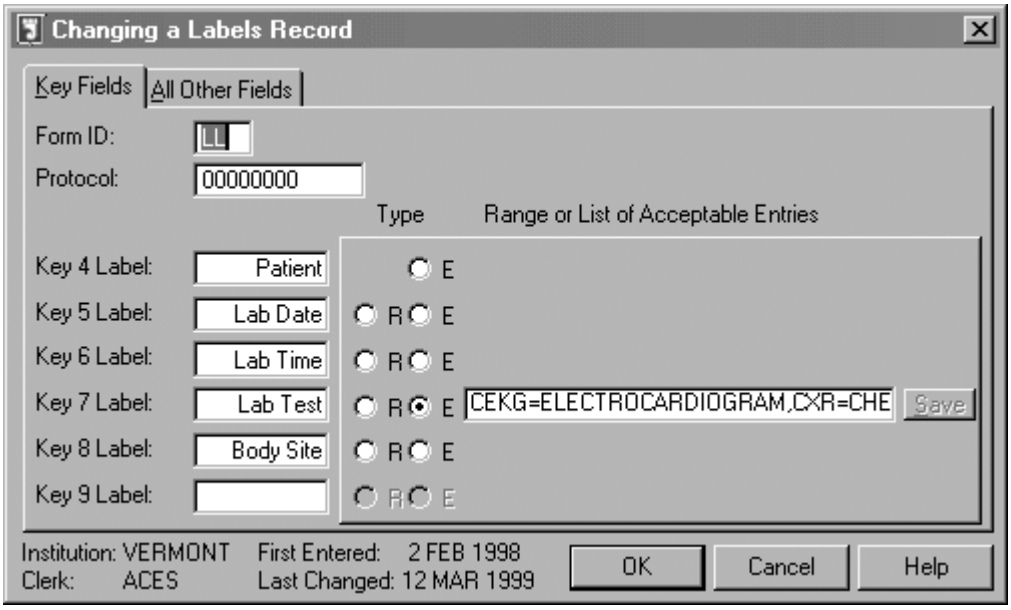
To insert a new record, click the Insert button and enter the key fields. After key field entry is complete, re-enter the record in “Change” mode to add the non-key field labels and all desired edit checks. Note that for files capturing laboratory information linked to the lab normals file (i.e. the “Uses Labcode ?” flag in the FormID record is equal to “Y”), simple ranges are not used for edit checking since multiples of the normal range values are automatically used instead.

Certain files in the standard database definition, EX and LX, are designed to allow multiple sets of field labels based on the protocol identifier and a code field called “panel”. In these cases, depending on which protocol and panel number is selected, different field labels will appear on the associated entry forms and reports. If you decide to add a new EX or LX file definition, please refer to an existing EX or LX file so that the correct fields are defined. In all study installations, at least one dummy EX and LX form has been included for reference purposes. In particular, the key fields for these files must be: FormID, Protocol, Patient, Date, Time, and Panel. In addition, for the EX file only, the first two non-key fields must be “SiteID for Labcode” (an eight character string), followed by a 4 digit integer “Labcode” field. All non-key fields after these must be pairs of fields with the first being data type “Real” and the second being a one character associated “Significant?” flag, for the EX file. For the LX file, all non-key fields must be defined with a “String” data type.

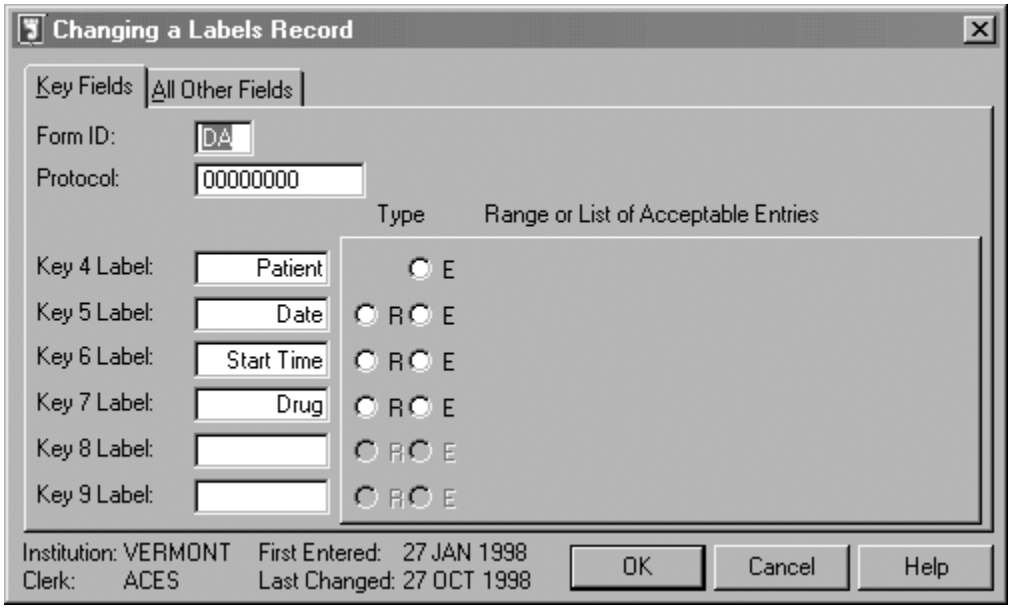
Several examples of various forms and associated edit checks are presented below.

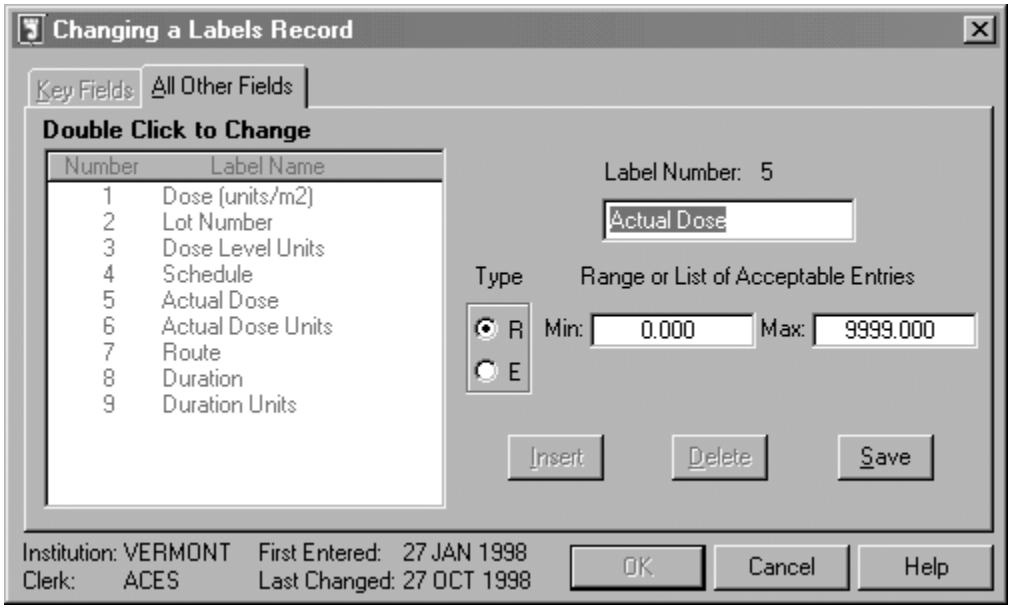

ACES - NEWCTMS Study. User: ACES Privilege: DB Purpose: CLERK
File Edit View! Extract Load Flag Window Help
Startup...
Usernames...
Configuration Options...
Export...
Operating Mode...
Print Reports...
Printer Setup...
Exit
Load Startup Data...
Edit Sequence
Edit Form ID File
Edit Field Labels and Lists of Acceptable Data
Delete Lists of Acceptable Data
Edit Field Types
Edit Length File
Modify Form Display
Browse the Labels File
Key Fields Are In Color
Form ID | Protocol | Panel | Key 4 Label | Key 5 Label | Key 6 Label | Key 7 Label | Key 8 Label
BC 00000000 Patient Lab Date Lab Time
BM 00000000 Patient Lab Date Lab Time
BS 00000000 Patient Onset Date Toxicity
CA 00000000 Patient Start Date
CI 00000000 Patient Start Date
CM 00000000 Patient Start Date Agent/Proc Item
DA 00000000 Patient Date Start Time Drug
EC 00000000 Patient
EN 00000000 Patient
EP 00000000 Subgroup T.A. Code Toxicity
EX 111-1111 0 Patient Lab Date Lab Time Panel
EX 222-2222 0 Patient Lab Date Lab Time Panel
Insert
Change
Delete
Close
Help
Add/Alter labels for all fields
Monday, September 27, 1999
2:11PM

This is a sample “LL” (literal lab) form with its associated key fields and edit check information.

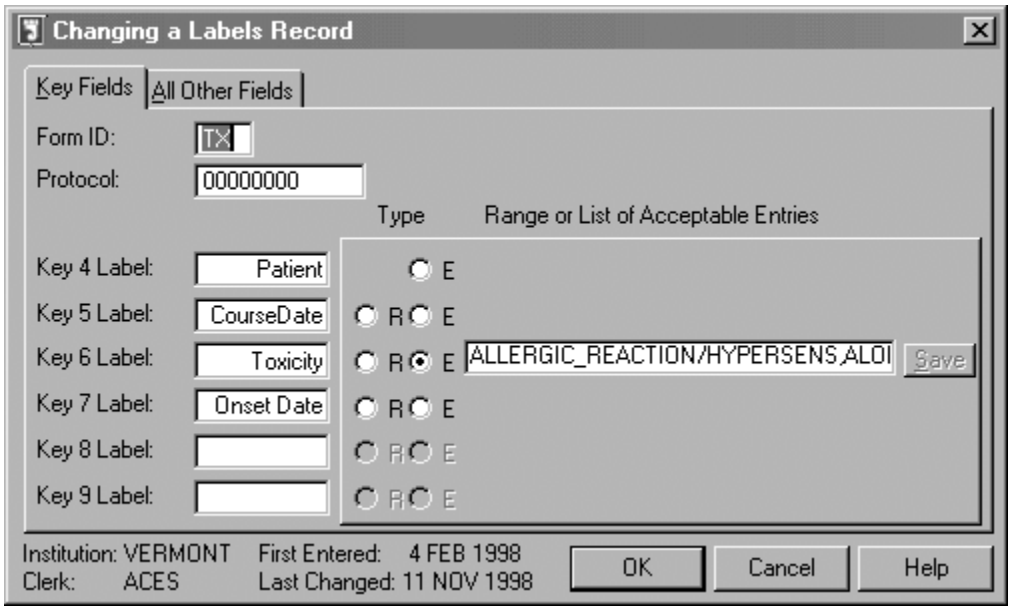


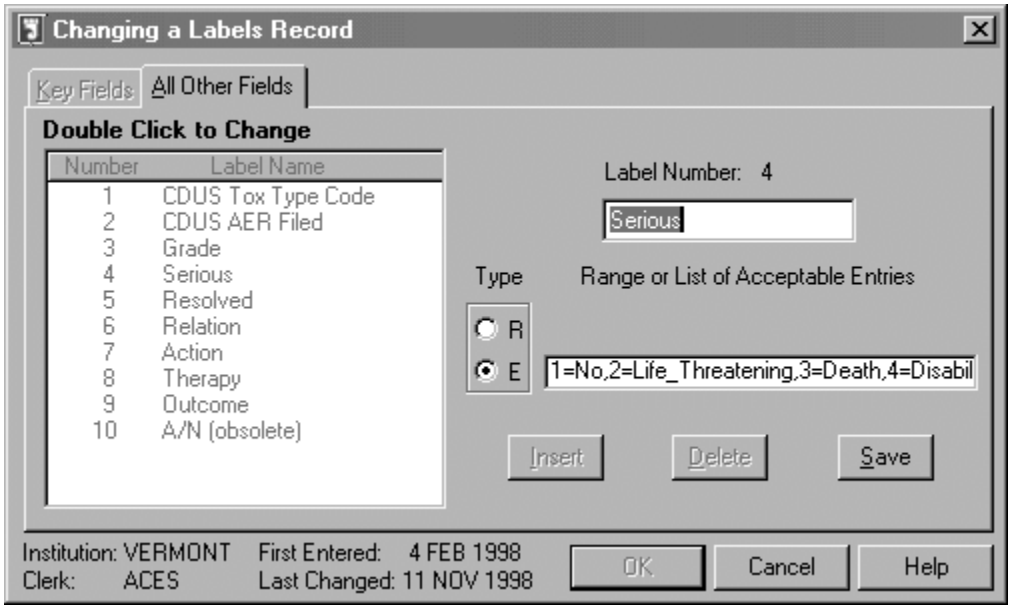
This is a “DA” (Drug Administration) form, with its associated key fields and edit checks, followed by a window containing the related non-key fields and edit check information.





This is a "TX" (toxicity, or adverse events) form with its associated key and non-key fields and related edit check information.





SPECIAL PICKLIST CODES

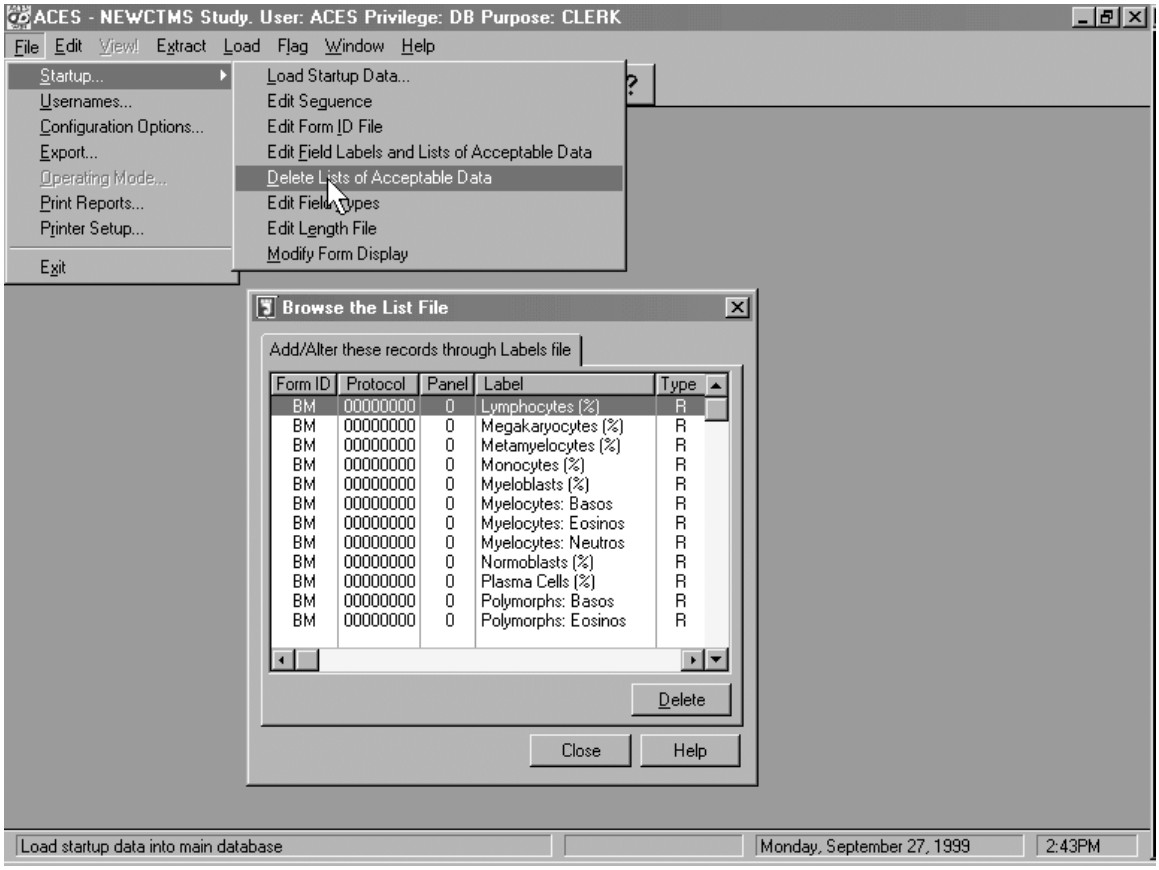
If a picklist ends with ",FREE!" then free text entry is allowed. This means that the picklist is just a guideline; it does not restrict entry at all. Note that FREE! must be the last entry in the picklist. For example, the picklist for the field Schedule in the DA form is QD,BID,TID,QID,QWK,PRN,q4h,q6h,q8h,q12h,FREE!. If a picklist begins with "+," then users may add new entries to the picklist during data entry. Finally, if a picklist begins with "!REQ," then the associated field is required; an entry must be chosen. Such a picklist might look like !REQ,1=Mild,2=Moderate,3=Severe,4=Life_Threatening,5=Fatal. Note that FREE! will cancel the effect of !REQ if both are included in a picklist.

DELETE LISTS OF EDIT CHECKS

From the “File” menu, select the “Startup” option, followed by the “Delete Lists of Acceptable Data” procedure. Use this procedure to delete edit check information. Note that this information is added and updated through use of the “Edit Field Labels and Lists of Acceptable Data” option, although the edit checks themselves are physically located in this separate “List” file. In general it will not be necessary to delete edit checks, but if needed, then this “Delete Lists of Acceptable Data” procedure must be used. If an edit check is of the "E" (list of acceptable entries) variety, it appears as a "footnote" in the datalisting report. If a field is removed from the structure of a form, but an associated "E" type edit check is not deleted in the "Delete Lists of Acceptable Data," it will still appear in the datalisting footnote. Additionally, if an edit check is "blanked out" while editing a Labels form, the edit check is blanked out but not deleted and will continue to affect data entry in perhaps unexpected ways.

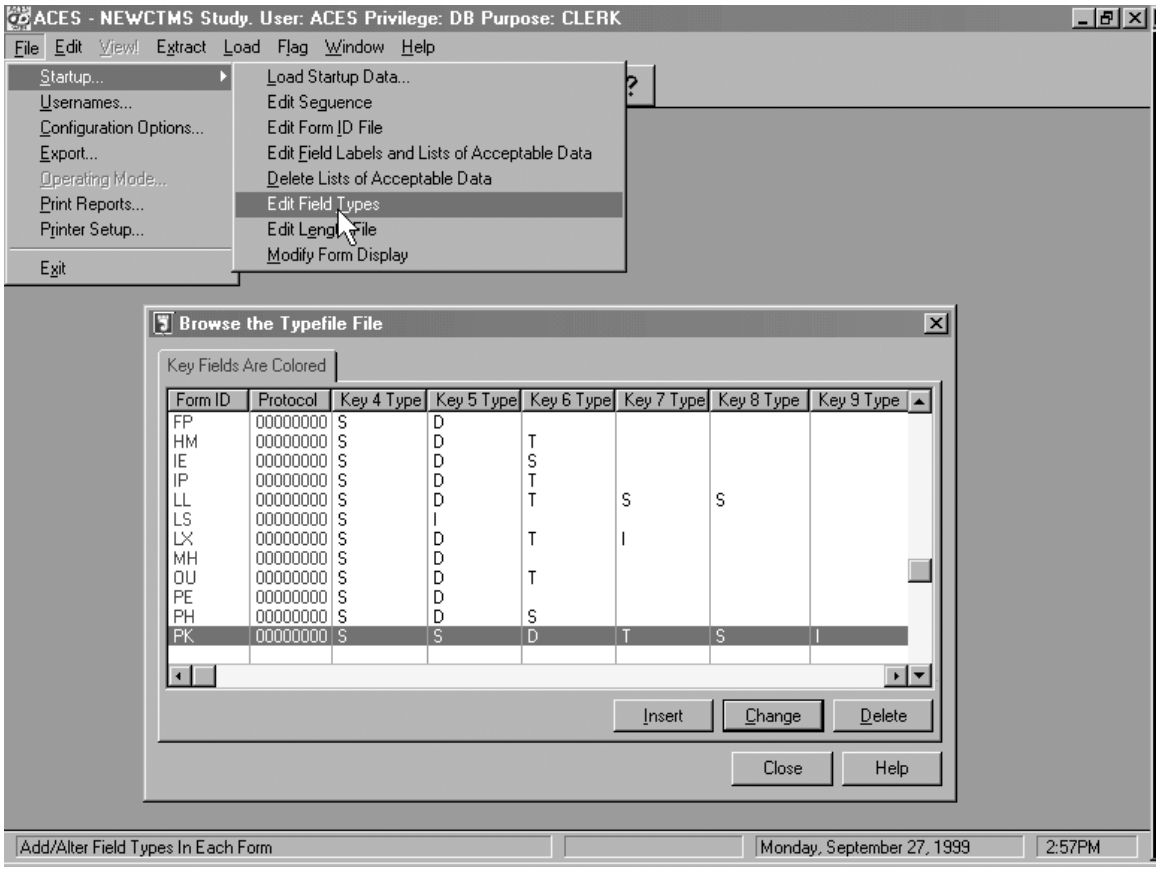
After deleting a picklist edit check (type E), it is important to bring up the associated Labels record in “Edit Field Labels and Lists of Acceptable Data”. Once the record is displayed, click on the OK button. This removes the underline from the field label, indicating that no picklist is available. For example, suppose a picklist for a field in the DA form is deleted. To remove the underline indicating the presence of this picklist, a user would need to update the DA record in the Labels file.

A sample window appears below:

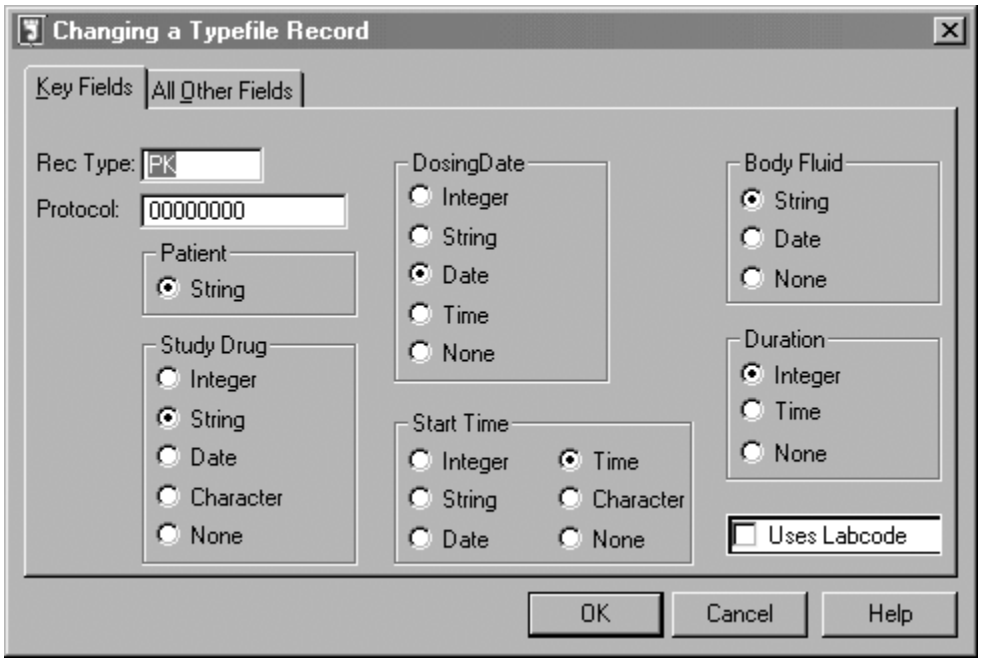


EDIT FIELD TYPES

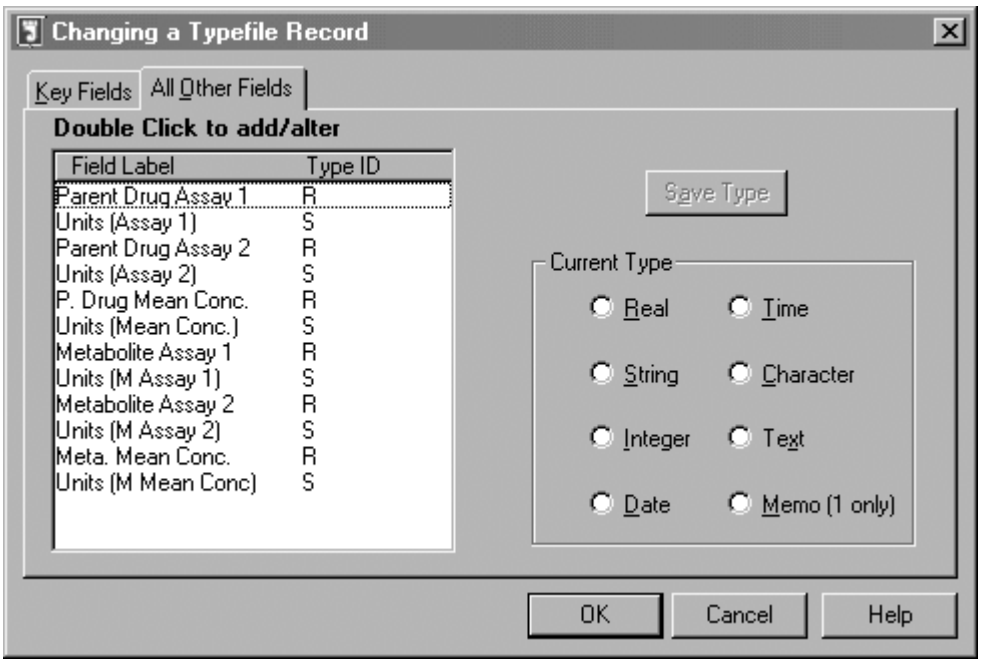
From the “File” menu, select the “Startup” option, followed by the “Edit Field Types” procedure to set these attributes for each form. Each field for every form used in a study must be assigned a data type. The choices are: “S” (string), “D” (date), “T” (time), “C” (character), “I” (integer), “R” (real), “X” (text), or “M” (memo). To change an existing record, highlight the target Form ID and click the Change button. You may also insert or delete these “Typefile” records. A sample browse window with the “PK” (pharmacokinetics) form highlighted is shown below:



Lab forms making use of the labcode (Normal ranges) facility must have the "Uses Labcode" checkbox checked. The first entry screen contains the key fields for the selected form as follows:



After assigning, or changing, the field types for the key fields, continue to the next screen on the second tab to edit the non-key field types. Only one memo field is allowed, and it must be the first and only non-key field. A non-key field longer than one character that has an associated picklist should be defined as a String. A sample of a non-key entry form for the “PK” form is shown below:



For related information on EX and LX, see "Multiple Lab/Literal Extra Forms In A Given Protocol."

EDIT FIELD LENGTHS

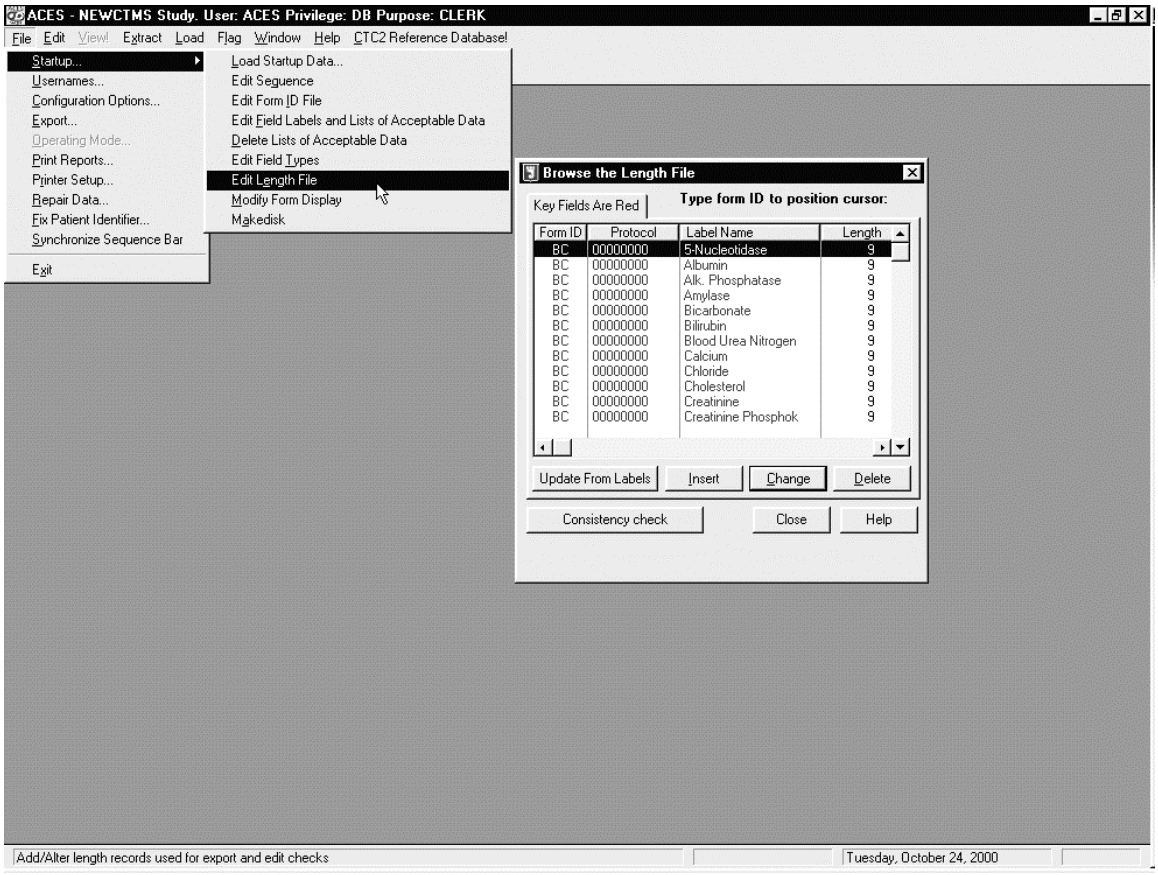
From the “File” menu, select the “Startup” option, followed by the “Edit Length File” procedure to set these attributes for each form. Allowable field lengths for the following types are described below:

String	1 – 24
Date	8
Time	4
Char	1
Integer	1 – 12
Real	4 – 10
Text	1 – 64
Memo	1 – 1024

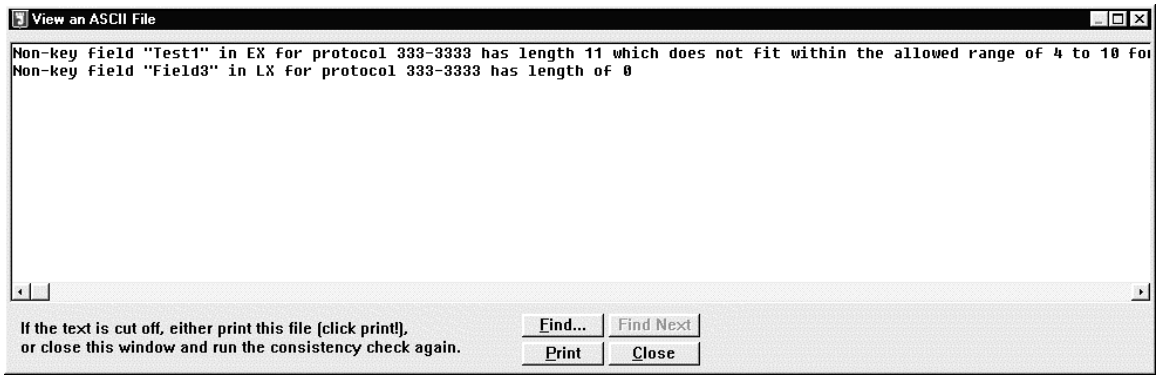
Floating Point Format (for Real type fields):

Length	Format
4	x.xx
5	xx.xx
6	xxx.xx
7	xxxx.xx
8	xxxx.xxx
9	xxxxx.xxx
10	xxxxx.xxxx

A sample “Browse the Length File” window is shown below:

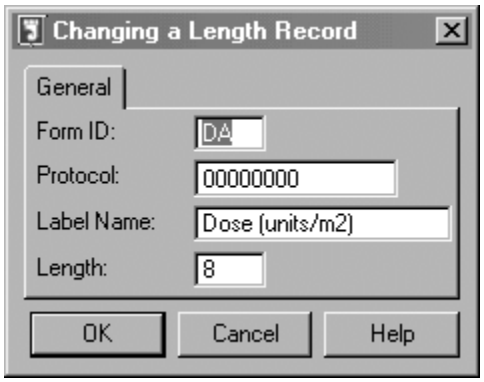


Clicking on the "Update From Labels" button will start a process that cycles through the entire Labels file, looking for labels that are not already present in the Length file. Records are added to the Length file for each of these "new" labels. After the process is complete, search through the browse listing for any records having 0 in the length column. Update these with the appropriate field length. Additionally or as an alternative to manual searching, click on the Consistency Check button. All Length file records will be analyzed by comparing the field’s type with its length. A report similar to the one below may be displayed.



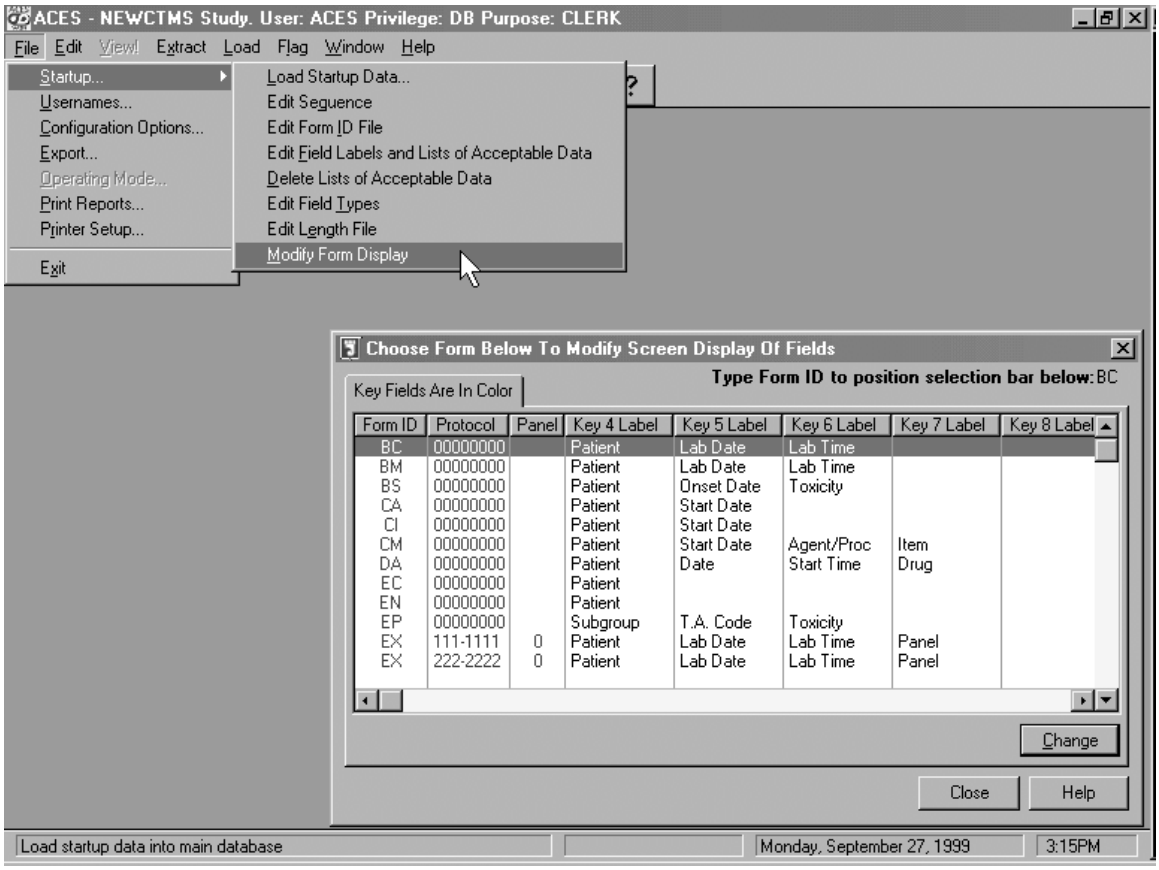
Fields with length 0 will be listed, as well as fields whose lengths violate the limits set for their particular type (see top of previous page for type length limits). This report may be sent to your printer. Whenever you finish designing a new form, running this consistency report is a good idea.

The entry form for the Length browse box would be similar to the following window for the "DA" (drug administration) form.



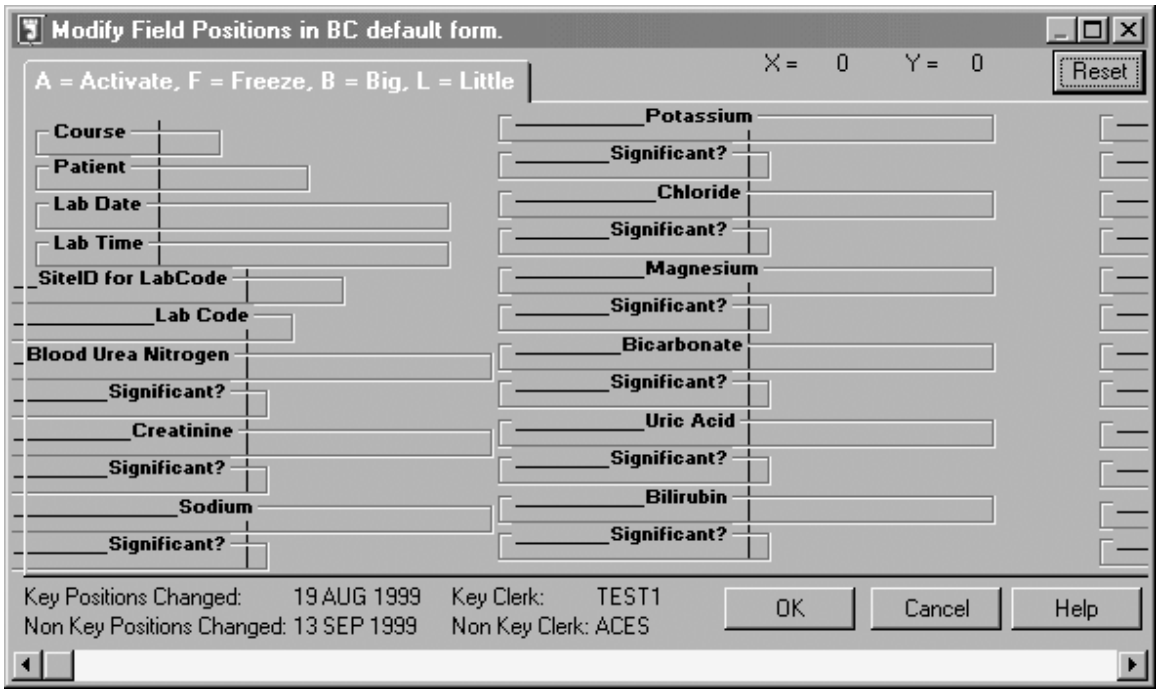
MODIFYING THE FORM DISPLAY

From the "File" menu, select the "Startup..." submenu, then choose "Modify Form Display." A sample "Choose Form Below To Modify Screen Display Of Fields" window is shown below:



You may move any of the field boxes anywhere you want on the tab. To move a field, place your mouse on the field and press the "A" key (for "activate") on your keyboard. The field will now follow your mouse, if you move it slowly. Though it is not required, it helps to keep your mouse's left button held down. When the field is in position, press the "F" key (freeze). The default movement amount is 1 screen unit. To increase the amount of space covered, press the "B" key ("big" movement). This will speed up the movement process, but will not allow for precise placement. Press the "L" key ("little" movement) for precision placement. Note the guidelines separating the prompt text from the actual field; lining these guidelines up will left justify the fields. If you move your mouse too fast and "lose" the field, simply move the mouse back onto the field. Once the "A" key is pressed, all fields are activated. Thus, be careful not to drag one field onto another; they will both move with the mouse. If this happens, press the "F" key to freeze the screen, then carefully place your mouse on a part of one field that is longer than the other field. Press "A" to activate and move the overlapping field away from the other. If the fields are the same length, it is possible to separate the fields by careful maneuvering.

Note that the tab is much larger than the window it is displayed in. There are vertical lines that should give you an idea of the boundaries of each "page." To move a field from one page to another, move it to the edge of the page, then click on the scroll bar below to scroll the tab in the direction of interest. Then continue to move the field. Below is a sample of the "BC" form:



Click OK when you are happy with the screen display. Be very careful about using the Reset button. It currently resets the fields to a very spread out, block style. Clicking on Reset is not reversible; it resets the form and closes the window.

DEFINING PROTOCOL SPECIFIC LAB FORMS

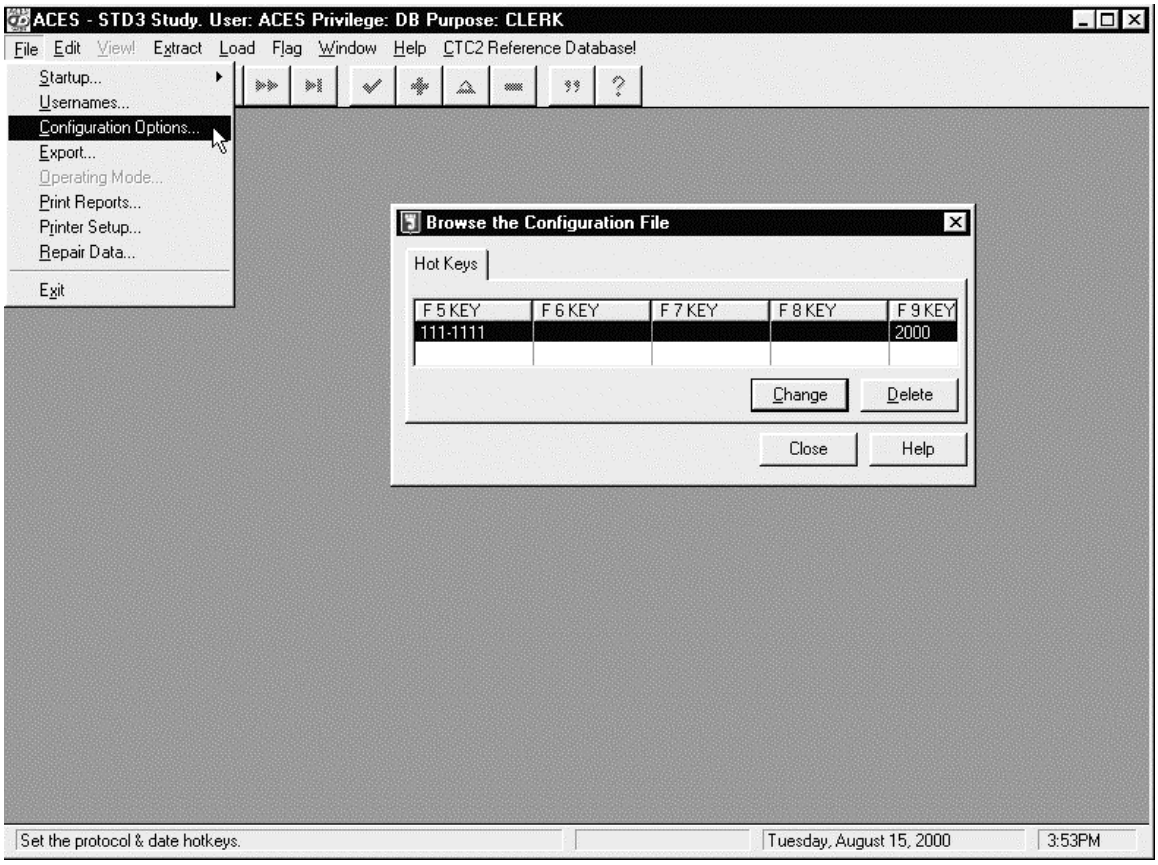
These instructions do not apply to the EX (Lab Extra) form. See "SPECIAL EX AND LX CONSIDERATIONS".

Adding a Protocol specific Lab form based on a current form

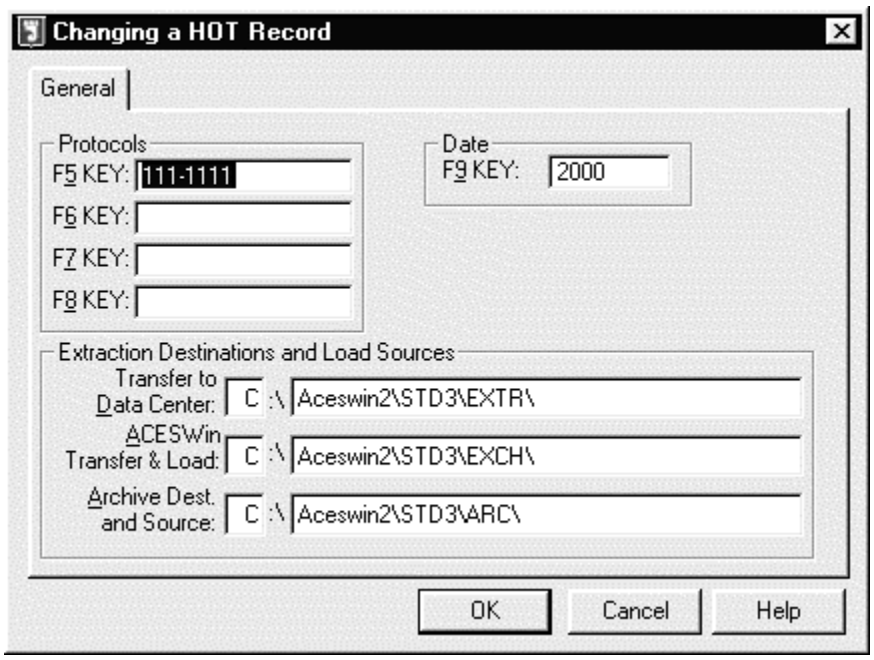
1. In the Labels Browse, update the current form that will serve as the basis for the protocol specific form.
2. Change the protocol number field to the target protocol number.
3. Update the non-key fields as desired, but with the following guidelines in mind:
   - If current tests will remain as is, add new tests at the end. This preserves the integrity of the units, leeway percentages, display order, conversion factors, and labcode ranges for the existing tests. Remember, the tabbing order for lab tests can be altered by choosing Lab Units in the Edit menu.
   - Fields may be deleted, but associated units, leeway percentages, display order, conversion factors, and labcode ranges will not likewise be deleted. All of these values will have to be adjusted accordingly.
   - Each new test MUST have a Significant? field inserted after it. This field label must be spelled and capitalized exactly as shown above.
   - If an existing test is to be replaced, remember to update the units, leeway percentages, display order, conversion factors, and labcode ranges.
4. Click on OK to save the record. Note that since the protocol number was changed (a key field for the Labels file), a new record was added, preserving the original record.
5. In the Typefile Browse (choose Edit Field Types in the Startup submenu of the File menu), update the record associated with the original Labels form.
6. Change the protocol number field to the target protocol number.
7. Click on the All Other Fields tab and note that the lab tests as defined in the new Labels record are now displayed here. Define field types for all untyped fields.
8. Click OK and note that again a record has been added instead of updated.
9. In the Length Browse, click on the Update from Labels button. After the process completes, there will be a record in the Length file for each record in the Labels file (existing Length records are NOT updated). Find the section of the list with the new protocol specific records.
10. Update each record with the appropriate length. Use the Length records from the original Label form as a guide. The lab tests should in general be 9 characters, the lab code should be 4, the SiteID for the Labcode should be 8, the Lab date should be 8, the Lab time should be 4, the Patient field should be 12, and the Significant? field should be 1.
11. Choose Lab Units in the Edit menu. Double click on the new protocol specific form record displayed in the browse.
12. New tests added at the end of the existing tests will NOT be marked with a green check. Click on each of these tests to specify the set of allowable units. The first unit will be used as the default and its conversion factor should be 1. The display order and leeway percentage may be set here as well. If any existing tests were changed (deleted, moved due to insertion, or replaced), the unit records of all tests after the changed tests should be checked, as well as those of the changed tests. When complete, click on the OK button to save the record. The program guards against duplicate order numbers.
13. Choose Labcodes (Normals) in the Edit menu. Either enter a new labcode record for the protocol specific form, specifying the protocol number in the labcode record itself, or follow the below instructions for modifying an existing labcode.
    - Copy an existing labcode record. Keep the existing protocol in the protocol field. Enter an appropriate Sex, then click OK.
    - Update the record that has just been copied. Now, enter the protocol in the protocol field and any other changes to the key fields. Select the browse box of the different lab tests to display the new labels from the protocol specific form. Make no changes to the lab test records, just click on OK to save the record.
    - Once again, update the record, this time making necessary changes and additions to the lab test records within the labcode record.

CONFIGURATION OPTIONS

The “Configuration Options” selection from the “File” menu allows you to set function keys to map to protocol numbers and the 4 digit year, and to verify the correctness of the data extraction and archive directories. In the example below, we have set the F5 function key to correspond to the protocol number 111-1111. This means that when we need to enter a protocol number anywhere in the ACES system, we can press the F5 key instead of entering the 111-1111 protocol number. Similarly, whenever we need to enter a 2000 year, we can press the F9 function key since 2000 has been mapped to it.

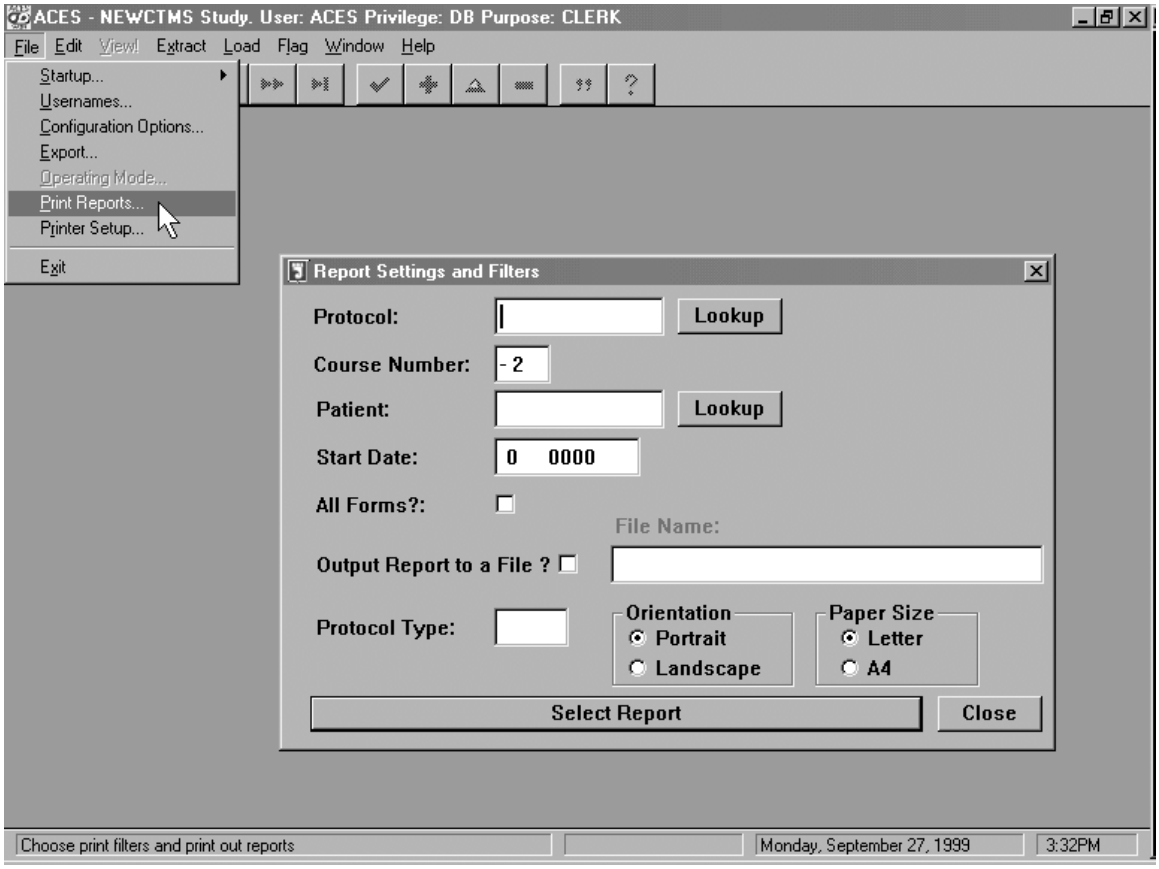


A sample entry screen for these “hot keys”, as well as for the default “Transfer to Data Center”, “ACESWin Transfer and Load”, and “Archive Destination and Source” paths, is shown below. For the paths, you’ll need to enter, at a minimum, the disk letter. In the window below, we have designated the “C” drive as our default disk drive, with the associated file paths. Another common configuration is to designate the “A” as the default drive for the “Transfer to Data Center” and “ACESWin Transfer and Load”, if you plan to use diskettes for these functions. Note that the “ACESWin Transfer and Load” specification is also used as the target destination for export files.



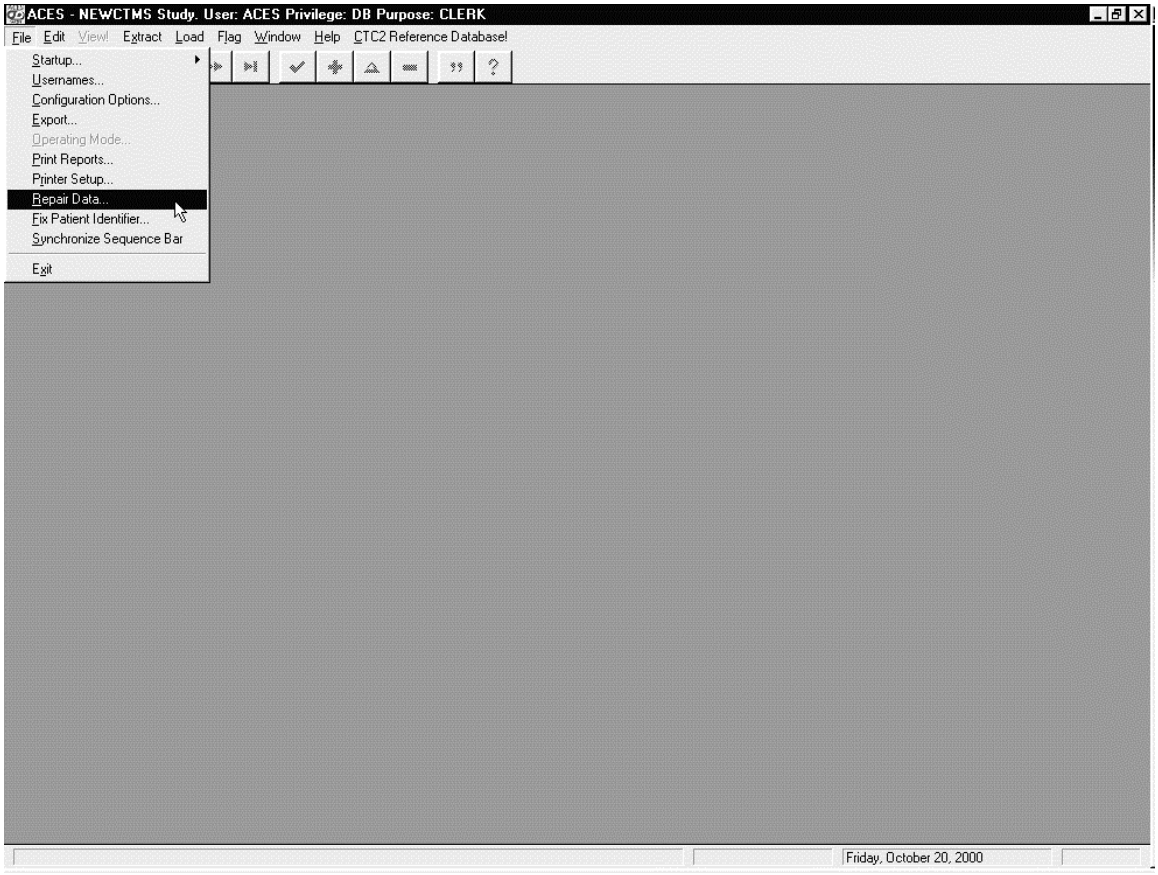
REPORTS

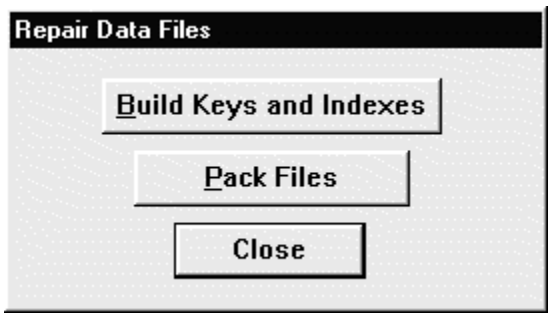
To print reports of your ACES® for Windows data, select the “Print Reports” option from the “File” menu. The first window will allow you to enter values to filter the data that will subsequently appear on reports. You can select data by protocol, patient, course, start date (this refers to the last changed date), and form. You may also select the report orientation, the paper size, whether to direct the report to a file, and the protocol type. After completing this screen, you can select a report from the list of available reports on the subsequent screen. A filter screen would be similar to the following:

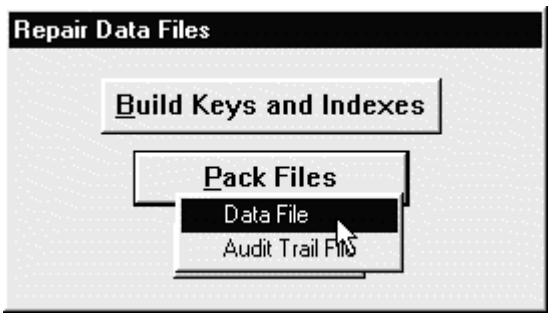


FILE REPAIR

To repair either the main clinical data or the audit trail data files select Repair Data… from the File menu.



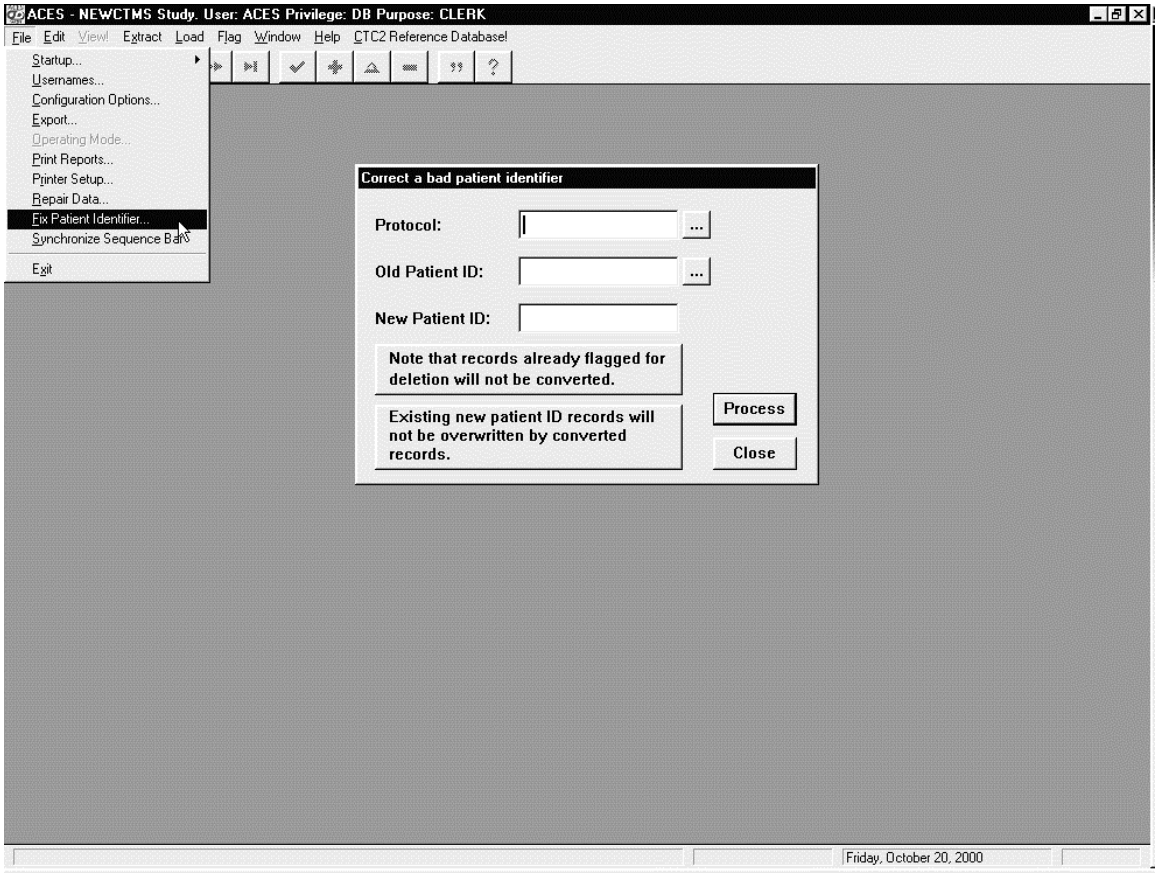




Clicking on either button brings up a popup menu that allows you to choose the operative file. Selecting Pack Files will create new copies of your data files **and** build the keys and indexes. If neither of these utilities fixes the corrupted file(s), you may need to restore your data from a backup.

FIX PATIENT

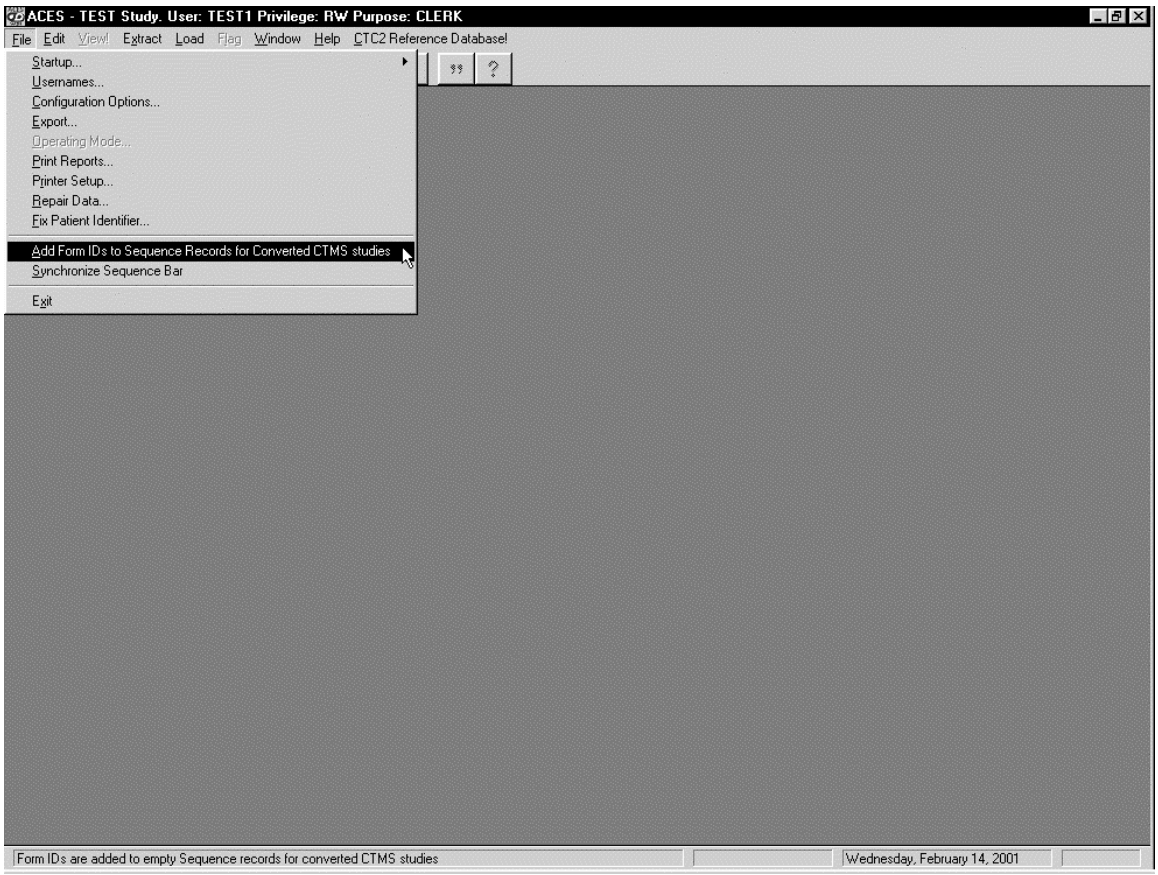
Choosing **Fix Patient Identifier** from the File menu opens up the following screen:



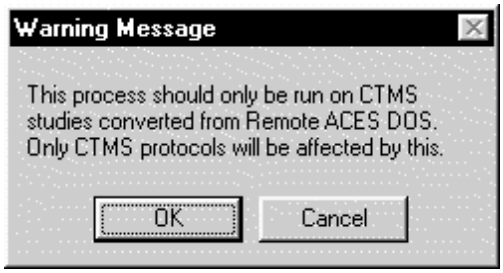
The protocol must exist in the Protocol Abstract file, just as the old patient ID must exist in the Patient file. The new patient ID may or may not be present in the Patient file. Clinical data already entered for the new patient ID will take precedence over any data with the same key structure entered with the old patient ID. Clicking on the Process button will cause new records to be created with the new patient ID from the existing non-deleted old patient ID records for the **entire database**. The old patient ID records will be flagged for deletion. The Sequence and Patient file records will also be updated (new records will be added with the same data the old records had). Old patient ID sequence records will not be deleted. Click on the Close button to close the window when finished.

BUILDING THE SEQUENCE FILE FOR A CONVERTED CTMS STUDY

CTMS studies that are converted from the old DOS program, Remote ACES, will have sequence file records devoid of any form IDs. Consequently, when a non-negative course number is entered in the Set Protocol, Patient, Course Number window, and the Go To DB Menu button is clicked, an empty sequence bar will appear. In order to populate the sequence bar with appropriate form IDs, you may choose "Add Form IDs to Sequence Records for Converted CTMS studies" from the File menu. Note that this process will ONLY affect empty sequence file records for CTMS studies.



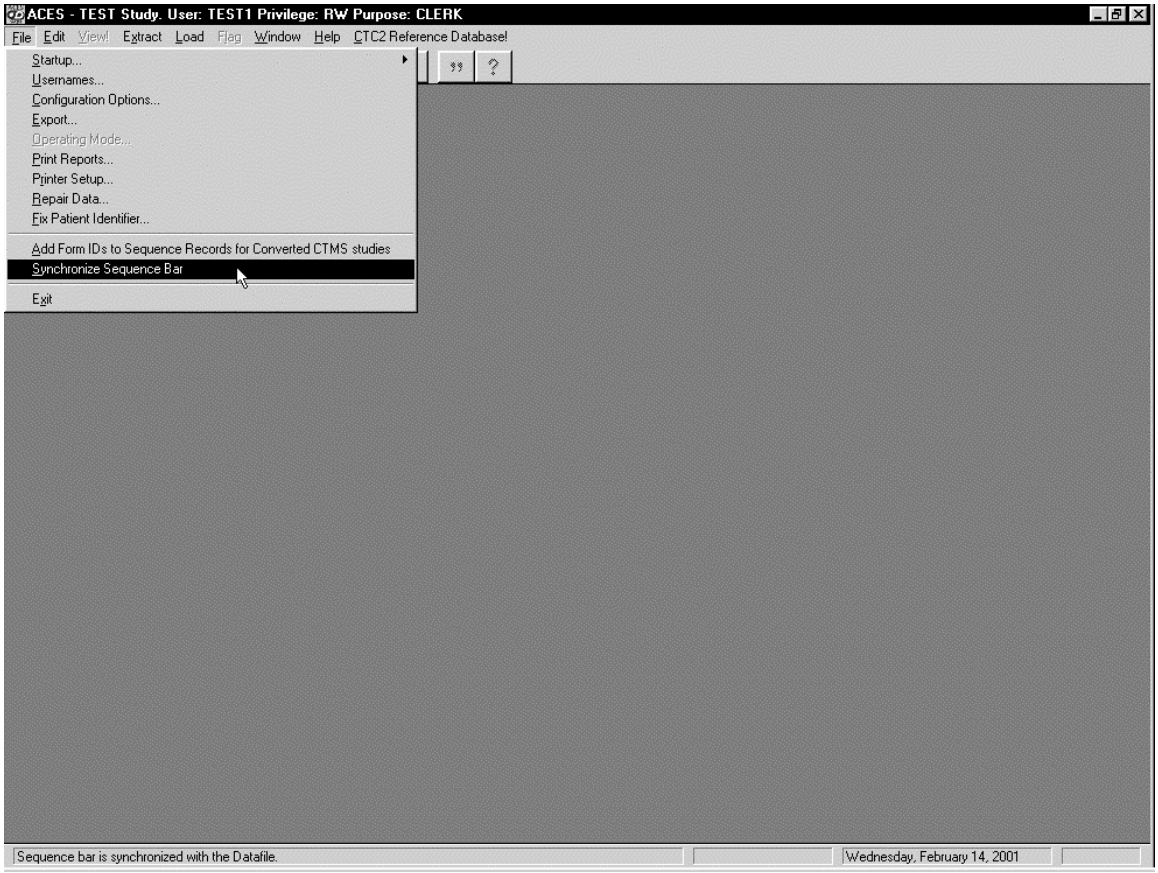
You will be warned once:



After the process is over, you may also run the Synchronize Sequence Bar process, but be aware that the accuracy of the Sequence bar depends on the course number as listed in each record. Converted data from the DOS ACES will have course numbers of –2 (meaning not entered) listed in most records. The Sequence bar has no connection to a course of –2. If you decide to synchronize the Sequence bar, you may wish to categorize each record in your ACESWin by course number before doing the synchronization.

SYNCHRONIZING THE SEQUENCE BAR

The sequence bar can lose its synchronization with the data entered if course numbers of forms are changed during form updates, or during a data load/import. To synchronize the sequence bar with the clinical data as it exists in the forms, choose Synchronize Sequence Bar from the File menu. There is no harm in doing multiple synchronizations.



HELP SYSTEM

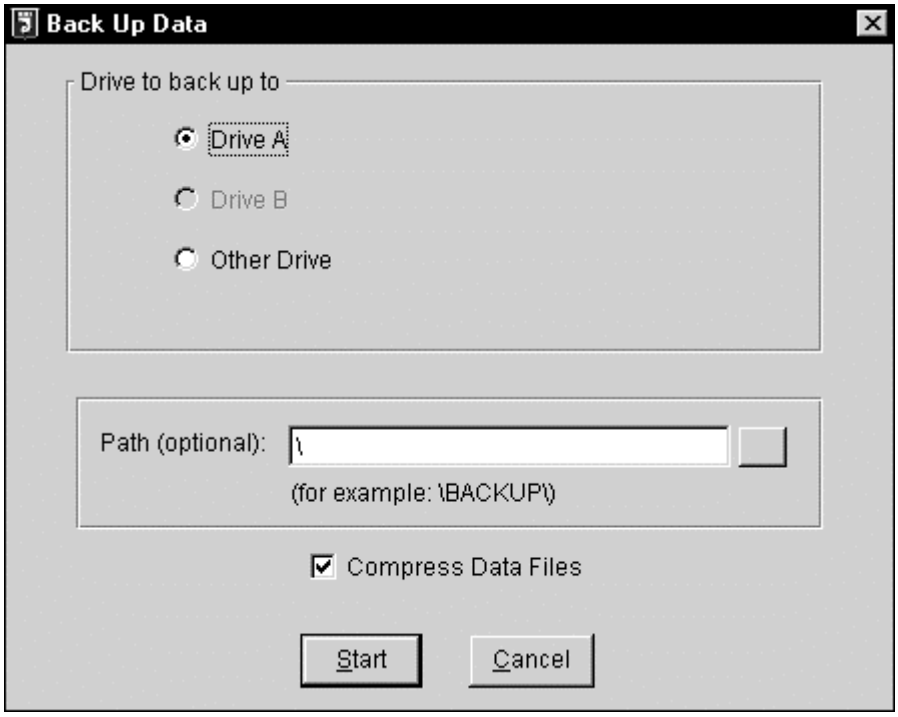
The ACES® system provides hypertext help when you choose one of the commands on the "Help" menu, or press the F1 function key. The text of the help system is, in general, the same as, or similar to, the printed documentation that comes with the software.

BACKING UP DATA

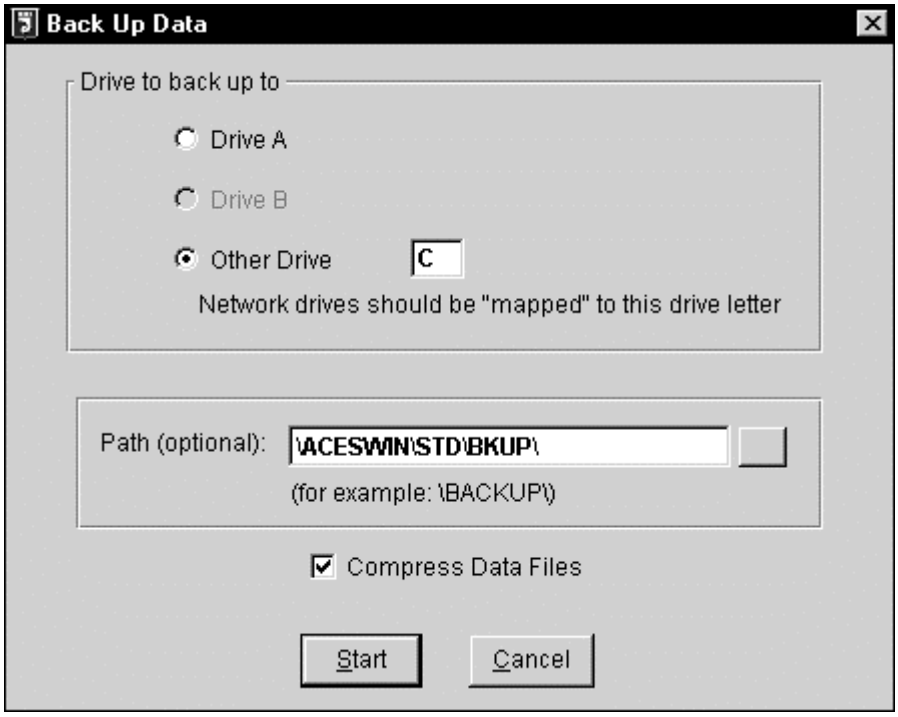
As information is entered into the ACES® system it is saved on disk. Events such as hardware failure, electrical interference, improper handling of diskettes, etc., could cause partial or complete loss of information. If the ACES® program becomes corrupted, it can always be re-installed from the original diskettes. However, if your data becomes corrupted, or lost, you'll need to restore it from a backup. We recommend that if your institution has a backup method, then that method be followed. If not, you can make use of the ACES® integrated backup procedure. Note that there are actually two sets of data to backup, your clinical data associated with a particular study, and the laboratory normal ranges data. The laboratory normal ranges database is shared by all studies, so it is backed up separately from the clinical study data. To use this system, perform the following steps:

1. Ask all users to exit the ACES® program, to free up all data files.
2. Select the "ACES for Windows" option from the Windows "Programs" menu.
3. Select the "Backup and Restore" option.
4. Click the "Backup Data" button (to backup your clinical study data), as shown in the sample screen below. (To backup lab normals, select the "Backup Normals" button)

Subsequently, the following window will be displayed, as shown below:



Click the destination drive and directory. If you will be backing up to diskettes, normally you will enter "A" as the drive letter, with no path. Then click the "Start" button to continue. Make sure the "Compress Data Files" box is checked. Alternatively, you can backup to a hard disk directory. ACES® for Windows is installed with subdirectories for each study called "BKUP" and "BKNORMS" which can be used if you'd like to make copies on your hard drive, instead of to diskettes. In the example below, we're backing up data for the STD study to the C:\ACESWIN\STD\BKUP directory.



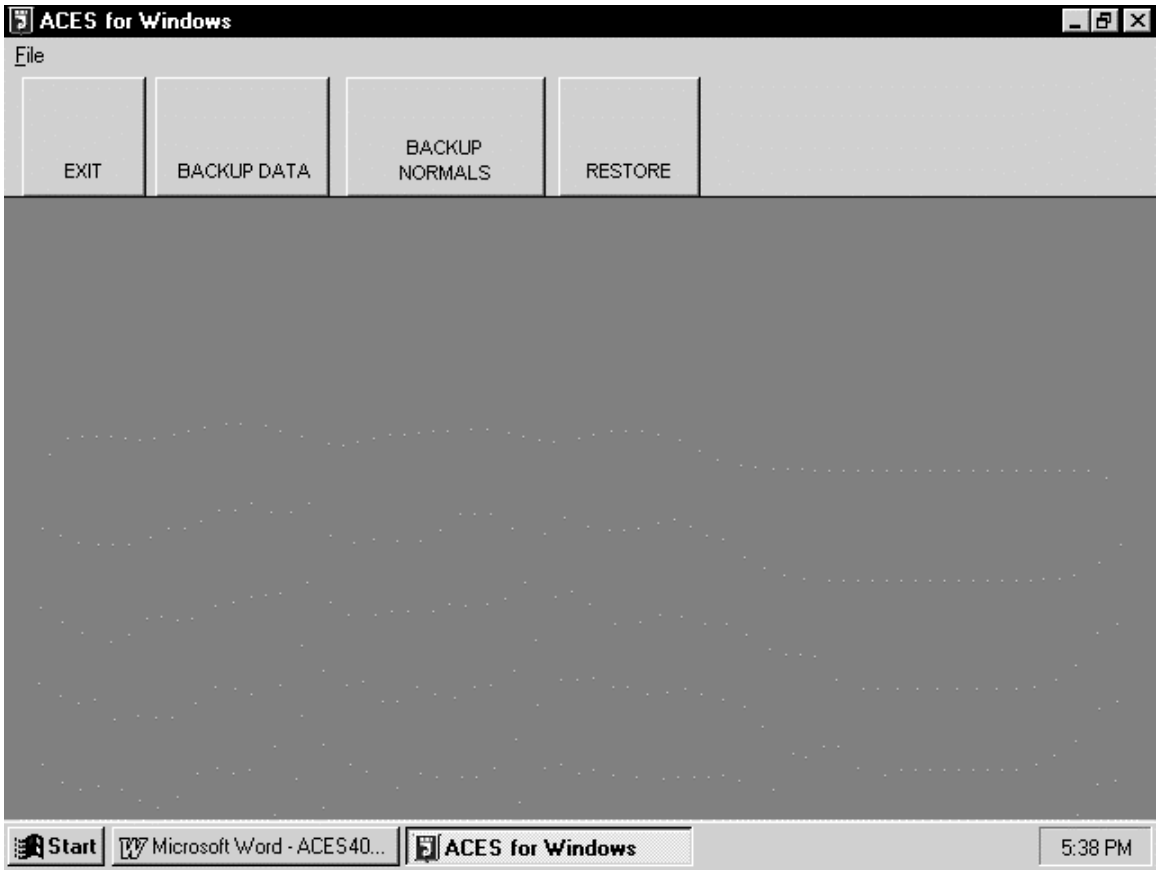
Subsequently, you will be prompted to select the study to be backed up in the “Select a Study” window. Then, the actual data path to be backed up will be displayed in a window. If correct, click the “OK” button to proceed. A sample for study STD would look similar to the following window:

The system will then compute the amount of data to be backed up. Click the “Continue” button to start the backup procedure.

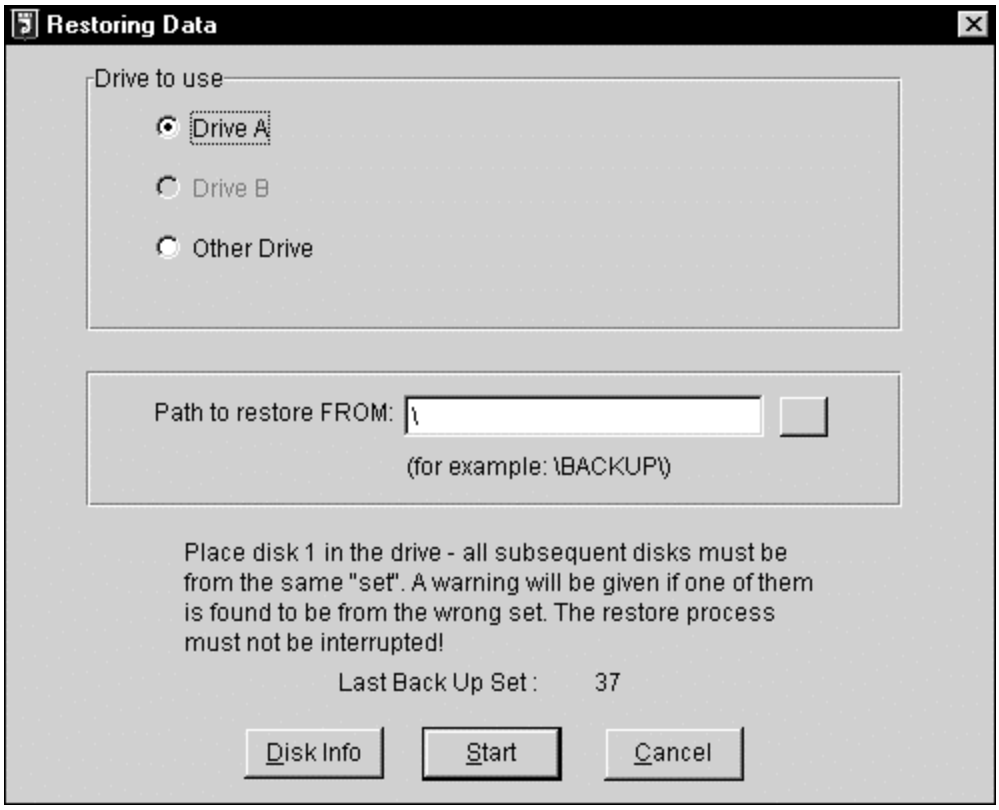
RESTORING DATA

To restore your database from a previous backup, perform the following steps:

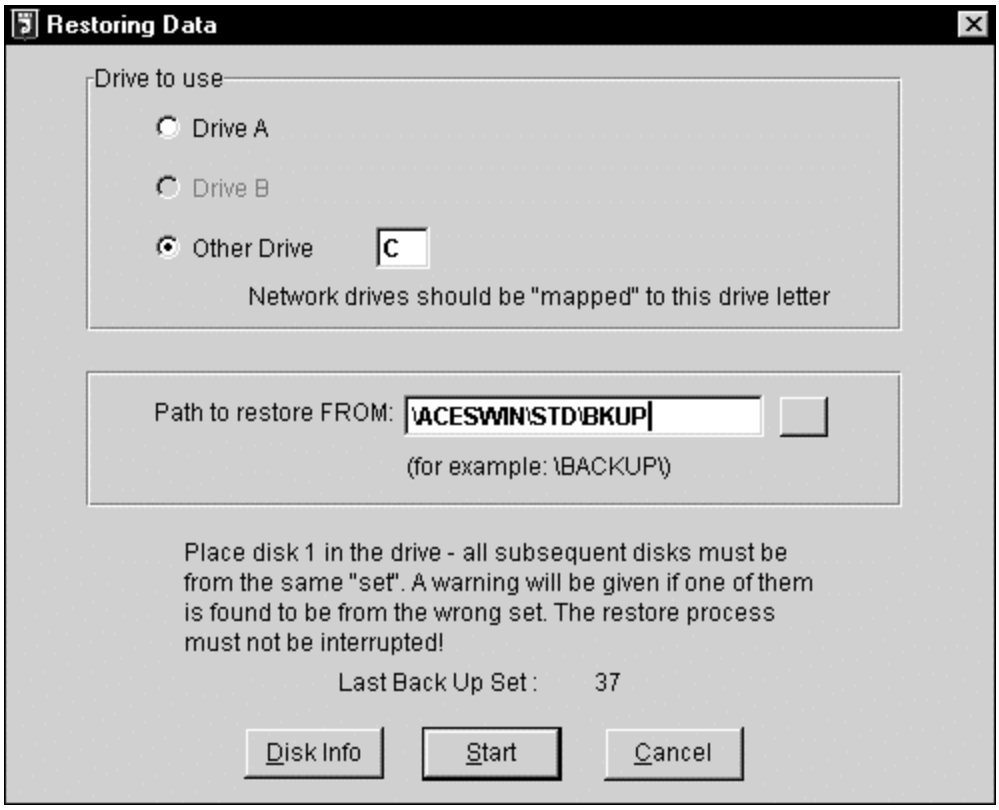
1. Ask all users to exit the ACES® program, to free up all data files.
2. Select the "ACES for Windows" option from the Windows "Programs" menu.
3. Select the "Backup and Restore" option.
4. Click the "Restore" button, as shown in the sample screen below:



Enter the source drive and directory. If you will be restoring from diskettes, normally you will enter "A" as the drive letter, with no path. Then click the "Start" button to continue. Note that the information in your backup will be restored to the same directory that it was backed up from. A sample window is shown below:



Alternatively, you can restore from a hard disk directory. In the example below, we're restoring data for the STD study from the C:\ACESWIN\STD\BKUP directory.



Click the “Start” button to proceed. Be aware that when you restore your database, you are restoring all data, not just a particular patient or form.

DATE FORMATS

All dates must be entered using the international date format, i.e. DD MTH YYYY where DD is the two digit day number, MTH is the 3 character month abbreviation (JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC), and YYYY is the four digit year. Certain date fields will allow coded values. Examples are as follows (a "-" means to enter a space):

Code Meaning	Entered	Displayed	Printed
"Not Entered"	-- NOT 0000	NOT 0000	00 NOT 0000
"Unknown" (only allowed in PT, PR, PS, TX, and CM files)	-- UNK	UNK 0000	00 UNK 0000
"Unknown Day/Mth" (only allowed in PT, PR, PS, TX, and CM files)	-- --- YYYY	YYYY	00 YYYY
"Ongoing" (only allowed in CM and TX files)	-- ONG	ONG 0000	00 ONG 0000
"Not Applicable"	-- NA	NA 0000	00 NA 0000
"Not Legible"	-- NL	NL 0000	00 NL 0000

Note that certain dates are designed to accept incomplete information. For example, the day of a prior surgical procedure may not be known.

A "hot key" can be programmed to the current year. If entered in the Configuration Options menu, you can press the F9 function key to insert the current year.

MISSING AND SPECIAL CODES FOR ENTERED DATA

ACES contains several sets of special codes that can be used to indicate why a certain field of data has missing or incomplete information. There are four categories of field types that have their own set of these codes; dates, times, literals, and numeric fields. The description of these codes is as follows (a "-" means to enter a space):

Dates:

Code Meaning	Entered	Displayed	Printed
"Not Entered"	-- NOT 0000	NOT 0000	00 NOT 0000
"Unknown" (only allowed in PT, PR, PS, TX, and CM files)	-- UNK	UNK 0000	00 UNK 0000
"Unknown Day/Mth" (only allowed in PT, PR, PS, TX, and CM files)	-- --- YYYY	YYYY	00 YYYY
"Ongoing" (only allowed in CM and TX files)	-- ONG	ONG 0000	00 ONG 0000
"Not Applicable"	-- NA	NA 0000	00 NA 0000
"Not Legible"	-- NL	NL 0000	00 NL 0000

Times:

Code Meaning	Entered	Displayed	Printed
"Not Entered"	-	:	:
"Unknown"	0	0:00	00:00
"Not Applicable"	NA	NA:	NA:
"Not Legible"	NL	NL:	NL:

Literals:

Code Meaning	Entered	Displayed	Printed
"Not Entered"	-		
"Unknown"	@	@	Unknown
"Not Done"	!	!	Not Done
"Not Applicable"	#	#	Not Applicable
"Not Legible"	%	%	Not Legible

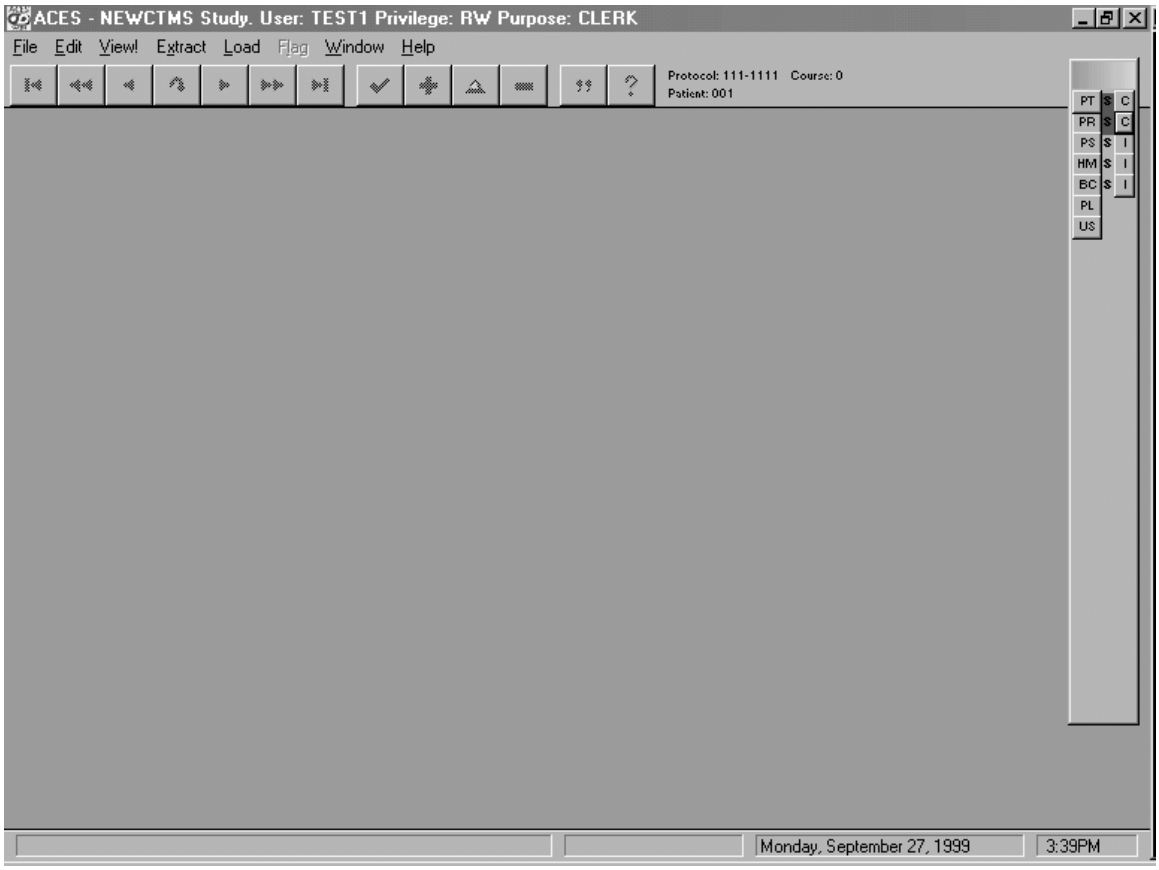
Note: For literal fields only if a value was previously entered into a field, and then spaced over to go back to the "Not Entered" value, then an "*" symbol will appear on the screen.

Numeric Fields:

Code Meaning	Entered	Displayed	Printed
"Not Entered"	-2	-2	
"Unknown"	-4	-4	Unknown
"Not Done"	-5	-5	Not Done
"Not Applicable"	-1	-1	Not Applicable
"Not Legible"	-3	-3	Not Legible

SEQUENCE BAR

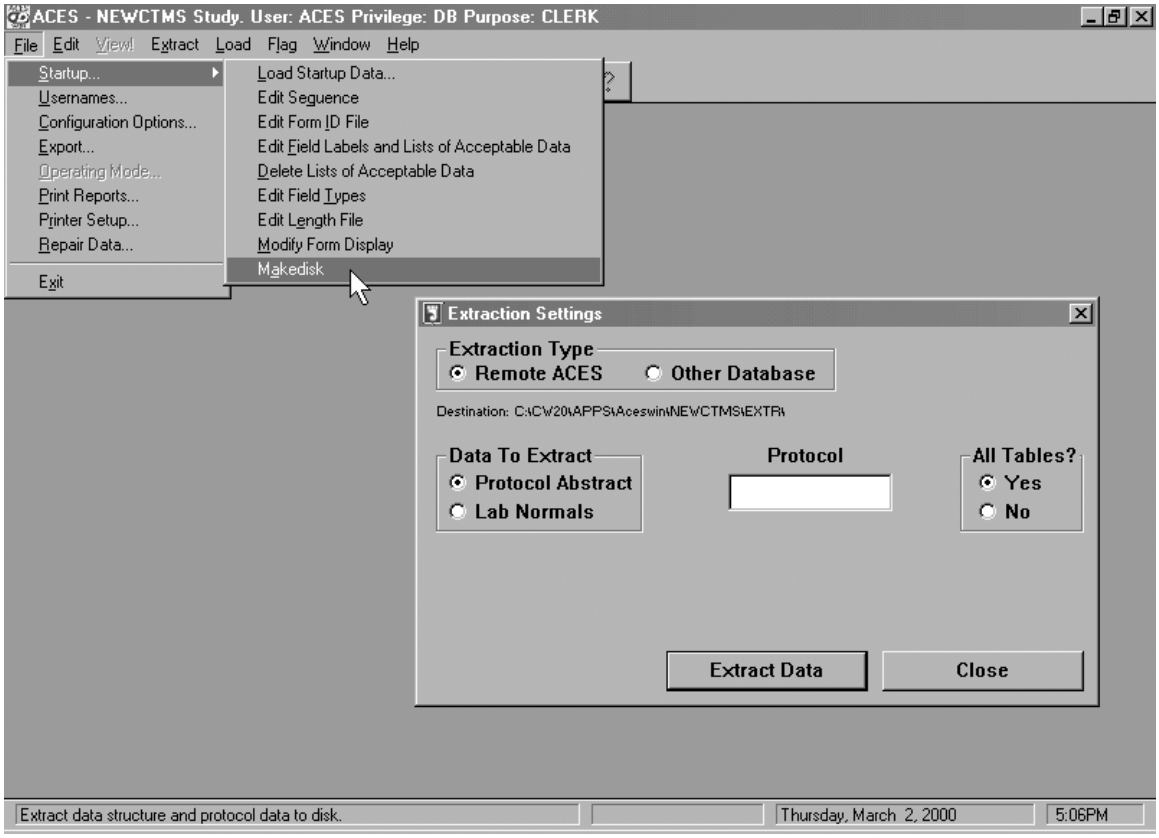
In order to keep track of which forms need to be completed for each patient and course, the ACES® program maintains a Sequence Bar. This is strictly a user guide; it does not prevent the completion of forms not listed for a given course. A vertical bar appears on the right side of the screen after protocol, patient, and course values have been selected from the "Set Protocol/Patient/Course" menu item. This bar consists of three columns of data. The first column shows the two character abbreviation for each form that needs to be completed for the selected patient and course. The second and third columns denote the status of that form. The second column is either blank (no entry has been done for the associated form) or has an "S" (entry has been started for the form). The third column is either blank (no entry has been done for the corresponding form), has an "I" (entry has been started, but is incomplete), or has a "C" (entry is complete). The values in the status columns are automatically set by ACES, EXCEPT for the "C" status flag. The data manager must decide whether entry for that patient, course, and form is completed. If so, the "I" box in the third column is clicked and it will change to a "C" status. Once all forms for a particular patient and course are flagged "completed", then when the patient and course are initially selected, the overall status indicator will also change to a "C" flag. This process will significantly aid the user in keeping track of how much entry remains to be done for a particular patient. Note that the sequence bar may be moved around the screen (as any window may) by pressing and dragging the shaded "title" top portion of the bar. A sample Sequence Bar is shown below:



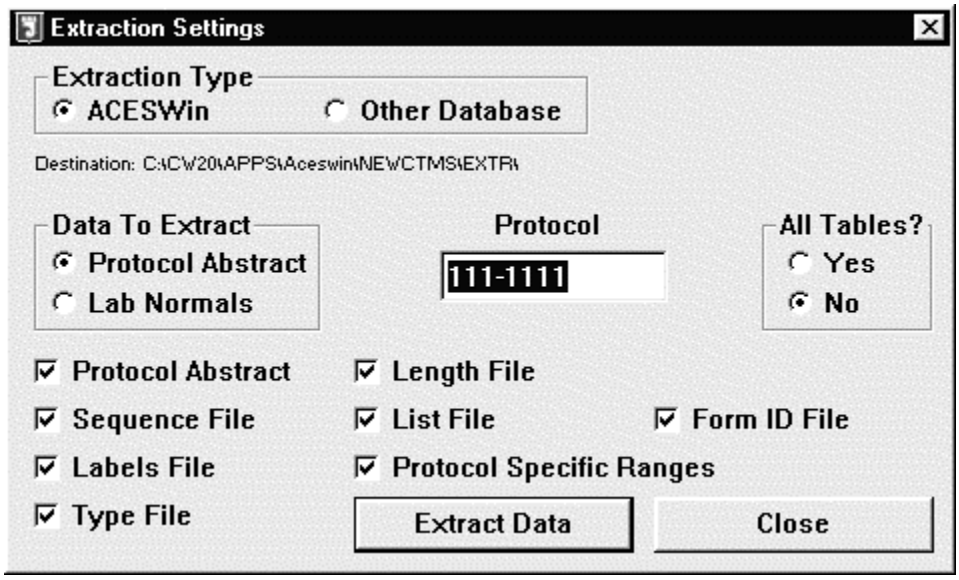
In this example, the PT (prior therapy) and PR (prior radiation) forms are complete, the PS (prior surgery), HM (hematology), and BC (blood chemistry) forms are in progress, and the PL (physical labs) and US (urinalysis) forms have no entry as yet for protocol 111-1111, patient 001, and course 0.

MAKEDISK

If you'd like to act as a central data center, and create your own Protocol and Lab Startup diskettes, you'll need to choose "Makedisk" at the bottom of the Startup… submenu of the File menu. The Protocol Startup disks can contain as little as protocol abstract and course sequence information, and as much as the details of an entirely custom defined database structure. Note that only a DB user may utilize the Makedisk option. Keeping the Extraction type as "ACESWin" will lead to files readable only by ACESWin. Choosing "Other Database" will produce ASCII files. It is usually more efficient to keep the destination as a hard disk, then copy the contents of the EXTR directory to a floppy disk (or attach to an email message). If using a floppy disk, clearly mark it with the appropriate Protocol identifier(s) or labcode number(s).



If Protocol Abstract is selected, enter the corresponding protocol identifier, and either "Yes" or "No" to transfer all data. Note that you can run this extraction twice, once for your specific protocol and once for the generic form protocol (00000000) if you need to transfer the entire ACESWin data structure somewhere. Of course, all ACESWin installations will already have the standard 00000000 structure.

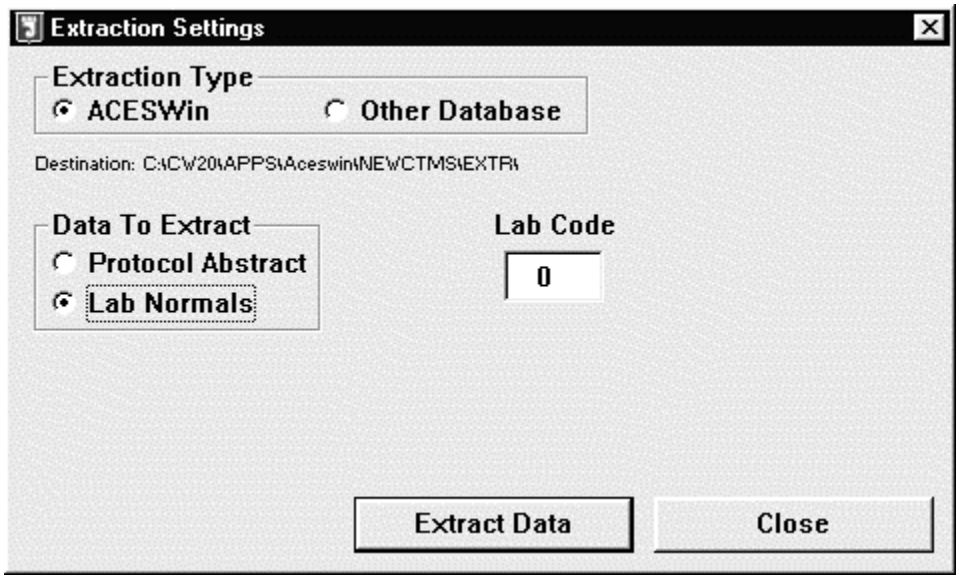


The files generated by MakeDisk are named based on the first eight characters of the protocol number entered in the above field. In the table below, the example protocol number of 111-1111 is used:

Above listed option	Files generated	Explanation, if any
Protocol Abstract	111-1111.pas Startmas.tps	Startmas.tps contains the site ID of the MakeDisk user.
Sequence File	111-1111.seq	
Labels File	111-1111.lbl 111-1111.kps	Labels are stored in the .lbl file, key field positions are in .kps file.
Type File	111-1111.typ	
Length File	111-1111.len	
List File	111-1111.lis	Contains picklists.
Protocol Specific Ranges	111-1111.exv	Labcode(s) for Lab Extra panels.
Form ID File	111-1111.fid	

Warning: If any testing has been done in this directory with real or test patient data, the Sequence file will be corrupted and should not be used to initialize or update an actual ACES study. If this has happened, exit out of ACESWin. Using the Windows Explorer or a DOS prompt, delete the files PAT.TPS and SEQUENCE.TPS in the Data subdirectory of the study directory you have been working in. Get back into ACESWin using your DB username and recreate the Sequence records for the study. **Note that you will have to recreate the entire Sequence file, including sequence records from other studies if they were stored in the same directory.**

If Lab Normals is selected, enter the associated lab code identifier.



AUDIT TRAIL

All clinical data entered into ACES® for Windows is kept in two places, the active database and the audit trail database. All edits and insertions applied to the active database are posted to the audit trail database. The only difference between the two databases is that the audit trail uses the change date and time as part of each record's key. Therefore, any time a record is added, changed, or flagged, a copy of the new version of that record will be *added* to the audit trail database, preserving a record of all prior versions.

CTC2 VERSION 2.0

The online version of this manual contains links from each of the below CTEP adverse event categories to the associated Common Toxicity Criteria (CTC) version 2.0 grading guidelines. In addition, links to the CTC2 Toxicity Module, Infection Module, Performance Status Scales/Scores, RTOG/EORTC Late Radiation Morbidity Scoring Scheme, and BMT Complex/Multi-Component Events are included.

ALLERGY/IMMUNOLOGY
AUDITORYHEARING
BLOODBONEMARROW
CARDIOVASCULAR (ARRHYTHMIA)
CARDIOVASCULAR (GENERAL)
COAGULATION
CONSTITUTIONAL SYMPTOMS
DERMATOLOGY/SKIN
ENDOCRINE
GASTROINTESTINAL
HEMORRHAGE
HEPATIC
INFECTION/FEBRILE NEUTROPENIA
LYMPHATICS
METABOLIC/LABORATORY
MUSCULOSKELETAL
NEUROLOGY
OCULAR/VISUAL
PAIN
PULMONARY
RENAL/GENITOURINARY
SECONDARY MALIGNANCY
SEXUAL REPRODUCTIVE FUNCTION
SYNDROMES
TOXICITY MODULE
INFECTION MODULE
PERFORMANCE STATUS SCALES/SCORES
RTOG/EORTC LATE RADIATION MORBIDITY SCORING SCHEME
BMT COMPLEX/MULTI-COMPONENT EVENTS